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(12) United States Patent
Bales, Jr. et al.

(10) **Patent No.: US 9,314,261 B2**
(45) **Date of Patent: Apr. 19, 2016**

(54) **BATTERY-POWERED HAND-HELD ULTRASONIC SURGICAL CAUTERY CUTTING DEVICE**

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(73) Assignee: **Covidien AG**, Neuhausen Am Rheinfall (CH)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/625,320**

(22) Filed: **Feb. 18, 2015**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Continuation-in-part of application No. 14/231,042, filed on Mar. 31, 2014, and a continuation-in-part of

(Continued)

(51) **Int. Cl.**

A61B 17/32 (2006.01)
A61B 19/02 (2006.01)
A61B 17/00 (2006.01)

(52) **U.S. Cl.**

CPC . ***A61B 17/320068*** (2013.01); ***A61B 17/320092*** (2013.01); ***A61B 19/0256*** (2013.01);

(Continued)

(58) **Field of Classification Search**

CPC A61B 17/320068; A61B 17/320092; A61B 2017/00137; A61B 2017/00199; A61B 2017/00734; A61B 18/1206; A61B 2018/00589; A61B 2018/00702; A61B 2018/00595; A61B 2018/00892; A61B 17/32; A61B 2017/00017

USPC 606/169, 39, 40, 45; 702/62; 600/437, 600/461, 471; 601/2; 604/22

See application file for complete search history.

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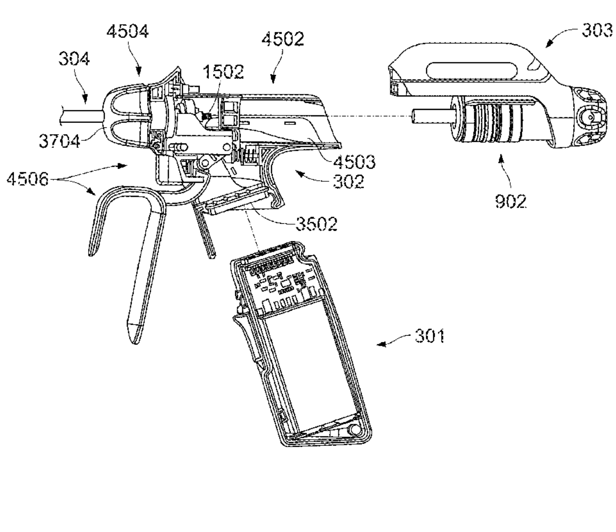
Primary Examiner — Katherine M Shi

(57) **ABSTRACT**

A battery-powered, modular surgical device comprising an electrically powered surgical instrument that requires a pre-determined minimum amount of electrical energy to complete a surgical procedure, and a power module assembly that has a battery that powers the surgical instrument and has a current state of electrical charge, and a control circuit that is electrically coupled to the battery and the surgical instrument and has a memory and a microprocessor. The microprocessor determines the current state of electrical charge of the battery, compares the current state of electrical charge to the pre-determined minimum amount of electrical energy, permits the battery to discharge if the current state of electrical charge is above the pre-determined minimum amount of electrical energy, and maintains the battery in a non-discharge state if the current state of electrical charge is below the pre-determined minimum amount of electrical energy.

20 Claims, 78 Drawing Sheets



Related U.S. Application Data

application No. 13/901,994, filed on May 24, 2013, now Pat. No. 8,742,269, and a continuation-in-part of application No. 13/655,571, filed on Oct. 19, 2012, now Pat. No. 8,487,199, and a continuation-in-part of application No. 13/655,557, filed on Oct. 19, 2012, now Pat. No. 8,497,437, and a continuation-in-part of application No. 13/655,532, filed on Oct. 19, 2012, now Pat. No. 8,502,091, and a continuation-in-part of application No. 13/655,522, filed on Oct. 19, 2012, now Pat. No. 8,497,436, and a continuation-in-part of application No. 12/868,545, filed on Aug. 25, 2010, now Pat. No. 8,334,468, application No. 14/625,320, which is a continuation-in-part of application No. 12/868,505, filed on Aug. 25, 2010, now Pat. No. 8,338,726, application No. 14/625,320, which is a continuation-in-part of application No. 13/874,010, filed on Apr. 30, 2013, now Pat. No. 9,084,625, and a continuation-in-part of application No. 13/873,958, filed on Apr. 30, 2013, now Pat. No. 8,992,555, and a continuation-in-part of application No. 13/539,694, filed on Jul. 2, 2012, and a continuation-in-part of application No. 13/465,820, filed on May 7, 2012, and a continuation-in-part of application No. 13/072,373, filed on Mar. 25, 2011, now Pat. No. 8,418,349, and a continuation-in-part of application No. 13/072,345, filed on Mar. 25, 2011, now Pat. No. 8,377,085, and a continuation-in-part of application No. 13/072,309, filed on Mar. 25, 2011, now Pat. No. 8,372,101, and a continuation-in-part of application No. 13/072,273, filed on Mar. 25, 2011, now Pat. No. 8,333,779, and a continuation-in-part of application No. 13/072,247, filed on Mar. 25, 2011, now Pat. No. 8,333,778, and a continuation-in-part of application No. 13/072,221, filed on Mar. 25, 2011, now Pat. No. 8,236,020, and a continuation-in-part of application No. 13/072,187, filed on Mar. 25, 2011, now Pat. No. 8,197,502, and a continuation-in-part of application No. 13/022,743, filed on Feb. 8, 2011, now Pat. No. 8,439,939, and a continuation-in-part of application No. 13/022,707, filed on Feb. 8, 2011, now Pat. No. 8,663,262, and a continuation-in-part of application No. 12/547,999, filed on Aug. 26, 2009, now Pat. No. 8,425,545, and a continuation-in-part of application No. 12/547,975, filed on Aug. 26, 2009, now Pat. No. 8,435,257, and a continuation-in-part of application No. 12/547,898, filed on Aug. 26, 2009, now Pat. No. 8,061,014, and a continuation-in-part of application No. 12/270,146, filed on Nov. 13, 2008, now Pat. No. 8,403,950, application No. 14/625,320, which is a continuation-in-part of application No. 12/269,629, filed on Nov. 12, 2008, now Pat. No. 8,403,949, application No. 14/625,320, which is a continuation-in-part of application No. 12/269,544, filed on Nov. 12, 2008, now Pat. No. 8,444,662, application No. 14/625,320, which is a continuation-in-part of application No. 12/266,664, filed on Nov. 7, 2008, now Pat. No. 8,372,099, application No. 14/625,320, which is a continuation-in-part of application No. 12/266,320, filed on Nov. 6, 2008, now Pat. No. 8,403,948, application No. 14/625,320, which is a continuation-in-part of application No. 12/266, 252, filed on Nov. 6, 2008, application No. 14/625,320, which is a continuation-in-part of application No. 12/266,226, filed on Nov. 6, 2008, application No. 14/625,320, which is a continuation-in-part of application No. 12/266,146, filed on Nov. 6, 2008, now Pat. No. 8,419,758, application No. 14/625,320, which is a continuation-in-part of application No. 12/266,101, filed on Nov. 6, 2008, now Pat. No. 8,419,757, application No. 14/625,320, which is a continuation-in-part of application No. 13/215,971, filed on Aug. 23, 2011, now Pat. No. 9,017,355, application No. 14/625,320, which is a division of application No. 13/307,750, filed on Nov. 30, 2011, now Pat. No. 9,107,690, application No. 14/625,320, which is a continuation-in-part of application No. 14/607,358, filed on Jan. 28, 2015.

(60) Provisional application No. 61/236,934, filed on Aug. 26, 2009, provisional application No. 61/081,885, filed on Jul. 18, 2008, provisional application No. 61/048,809, filed on Apr. 29, 2008, provisional application No. 61/045,475, filed on Apr. 16, 2008, provisional application No. 61/019,888, filed on Jan. 9, 2008, provisional application No. 60/992,498, filed on Dec. 5, 2007, provisional application No. 60/991,829, filed on Dec. 3, 2007, provisional application No. 61/376,893, filed on Aug. 25, 2010, provisional application No. 61/476,022, filed on Apr. 15, 2010.

(52) **U.S. Cl.**
CPC . *A61B2017/0038* (2013.01); *A61B 2017/0046* (2013.01); *A61B 2017/00137* (2013.01); *A61B 2017/00199* (2013.01); *A61B 2017/00367* (2013.01); *A61B 2017/00389* (2013.01); *A61B 2017/00402* (2013.01); *A61B 2017/00415* (2013.01); *A61B 2017/00734* (2013.01); *A61B 2019/028* (2013.01)

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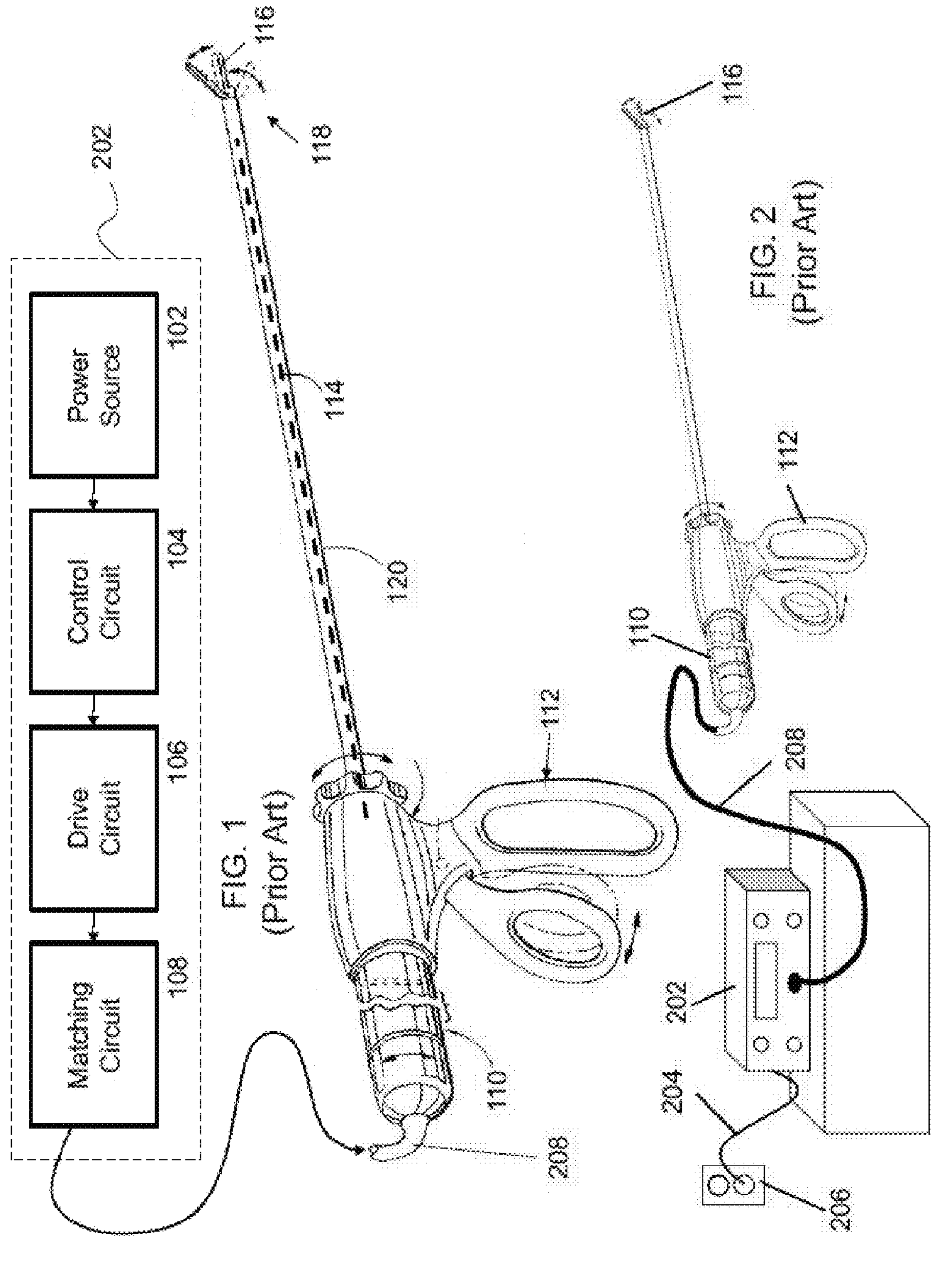
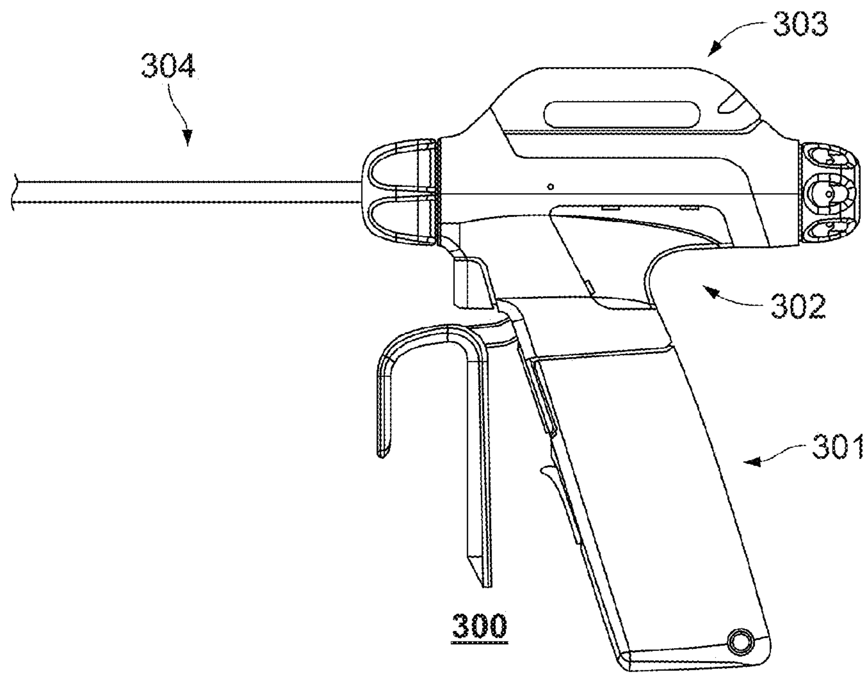


FIG. 1 (Prior Art)

FIG. 2 (Prior Art)



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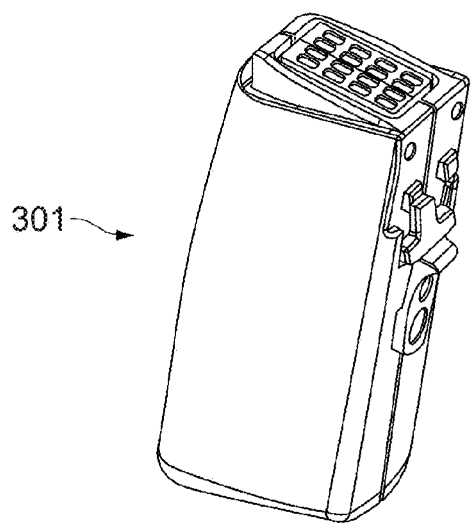

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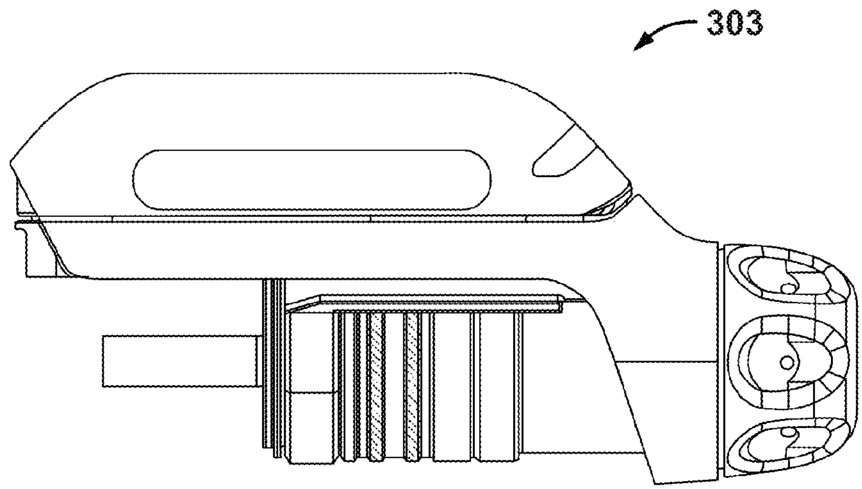

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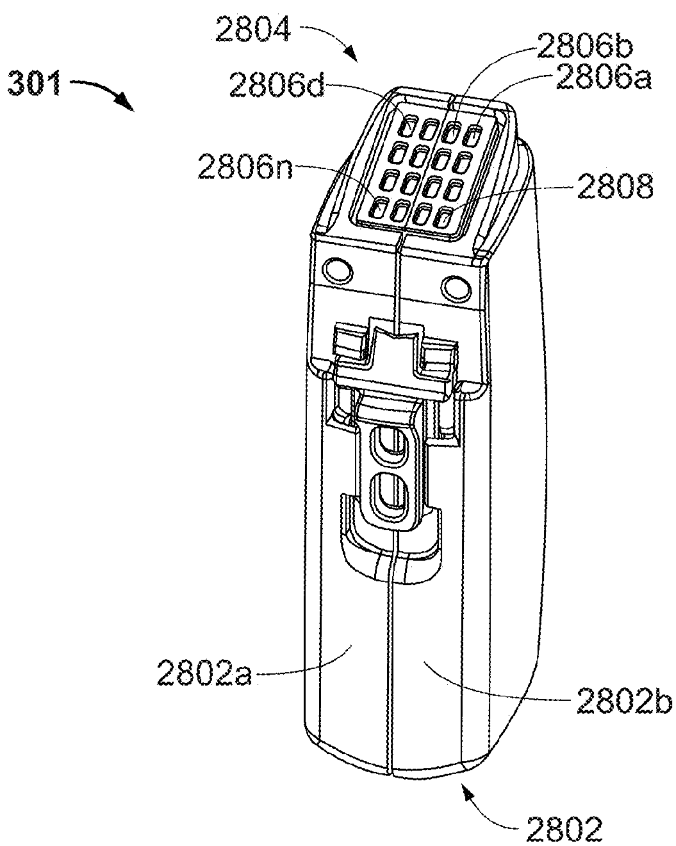
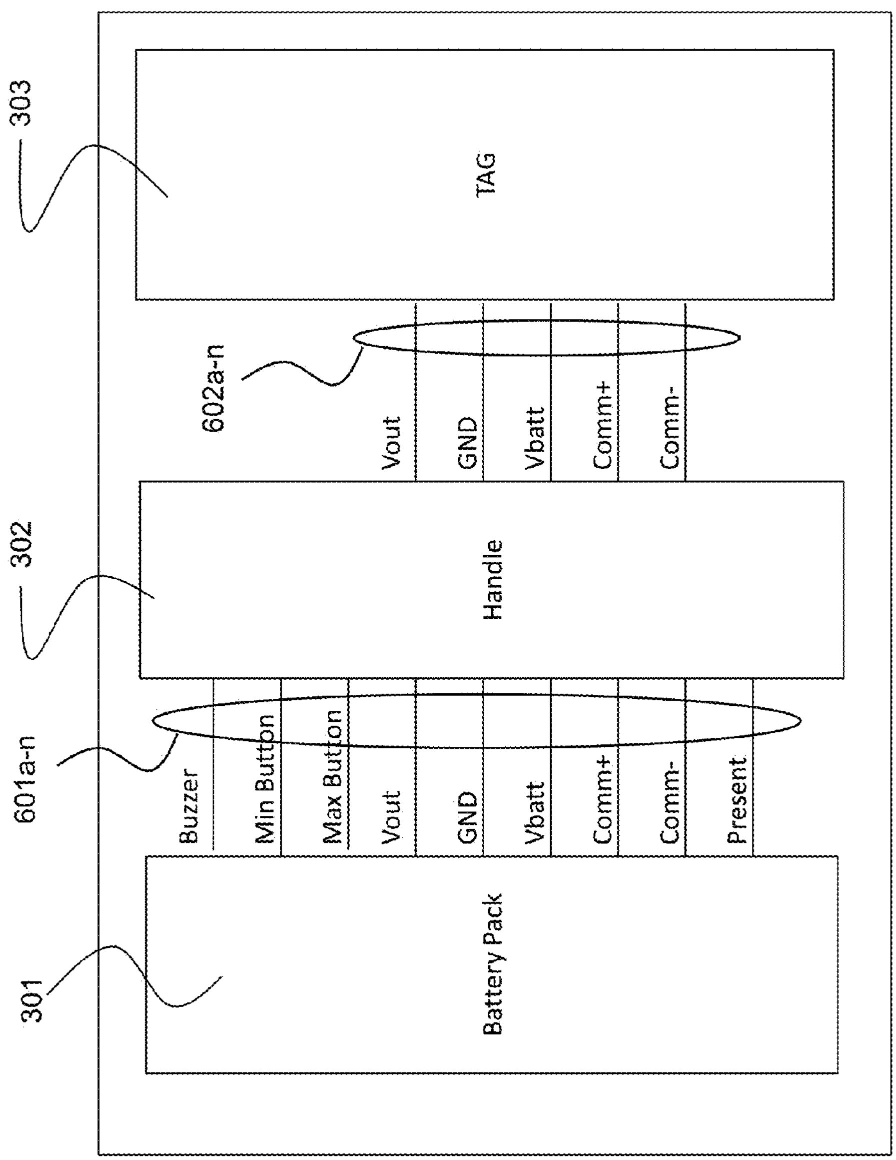


FIG. 28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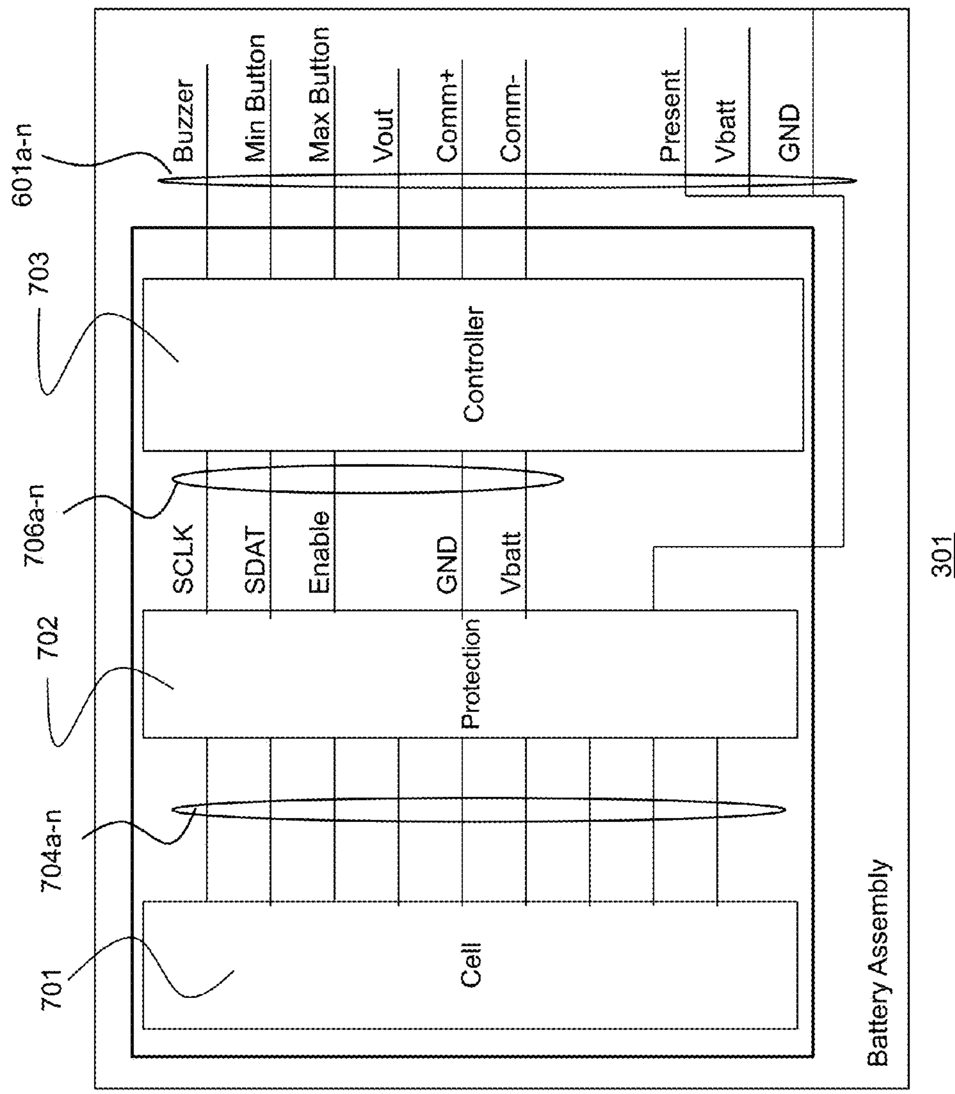
TAG
602a-n
Vout
GND
Vbatt
Comm+
Comm-
302
Handle
601a-n
Buzzer
Min Button
Max Button
Vout
GND
Vbatt
Comm+
Comm-
Present
301
Battery Pack

300

FIG. 6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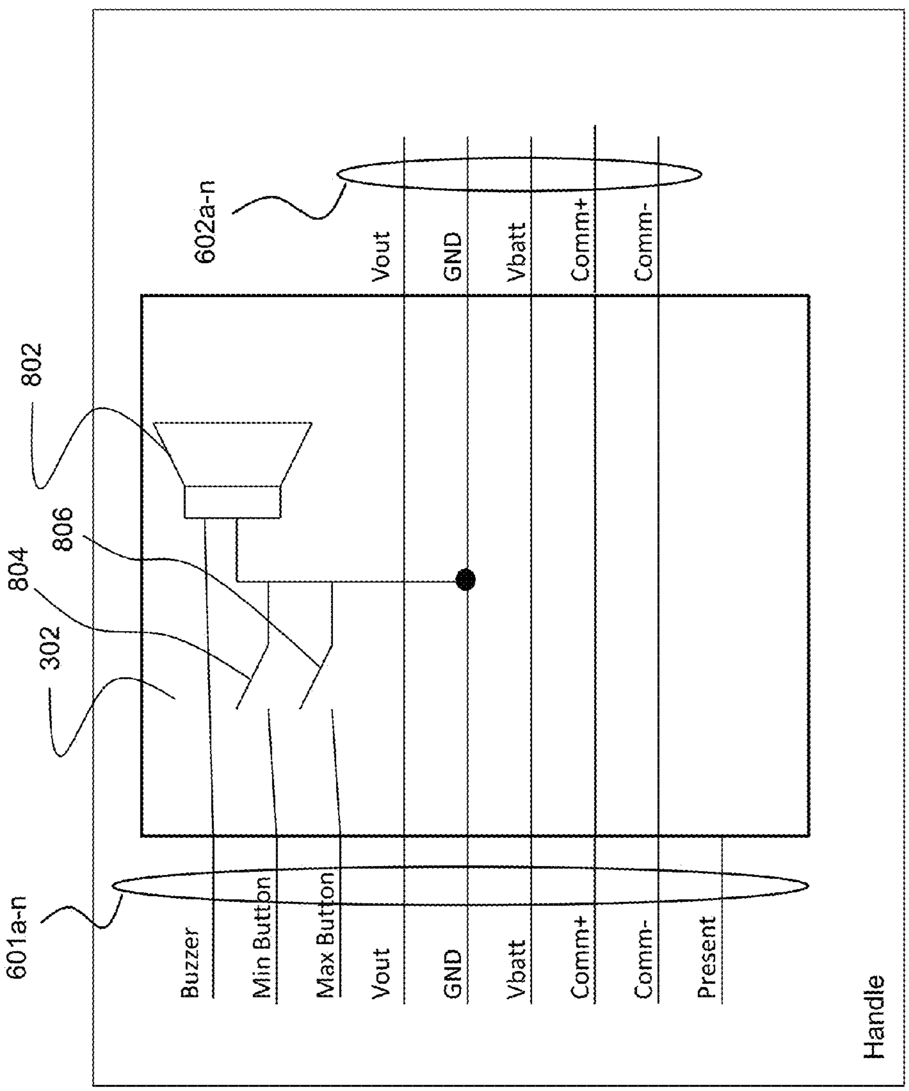
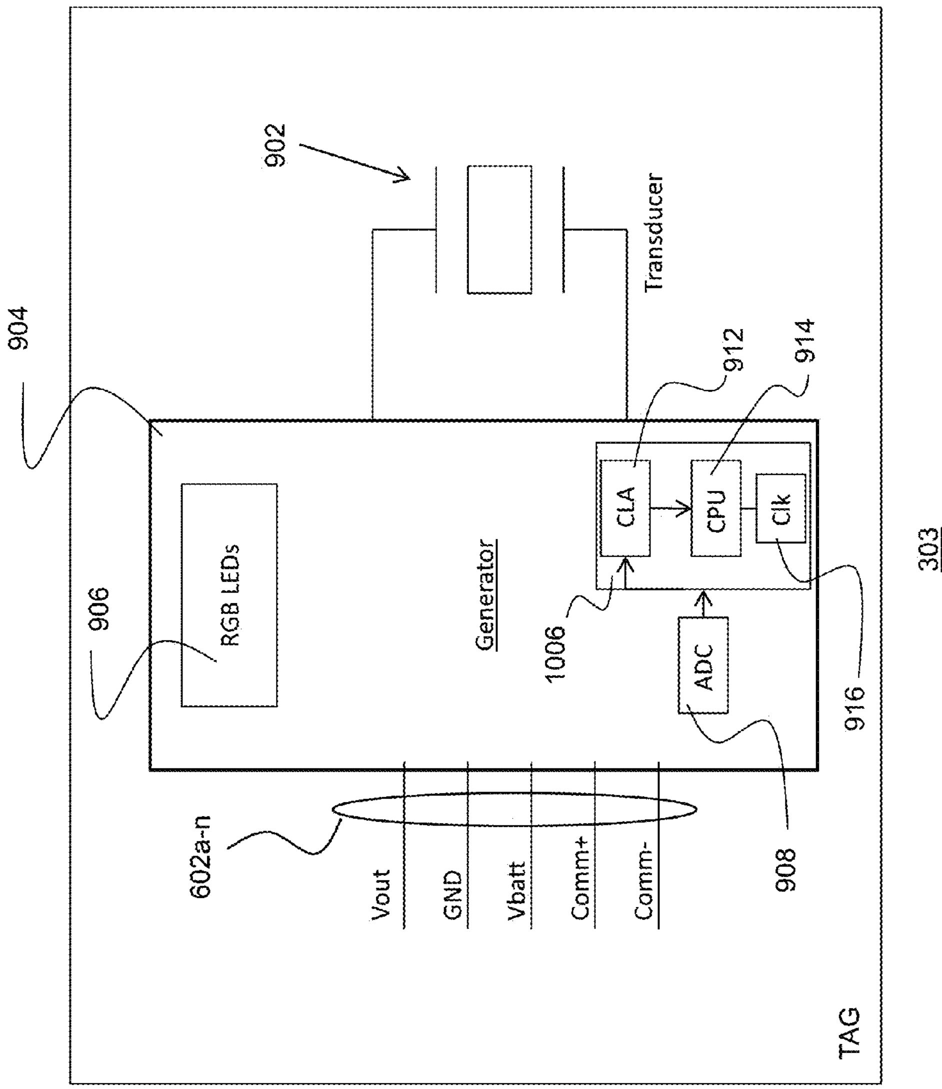
Buzzer
Min Button
Max Button
Vout
Comm+
Comm-
Present
Vbatt
GND
703
Controller
706a-n
SCLK
SDAT
Enable
GND
Vbatt
702
Protection
704a-n
701
Cell
Battery Assembly
301

FIG. 7


602a-n
Vout
GND
Vbatt
Comm+
Comm-
802
806
804
302
601a-n
Buzzer
Min Button
Max Button
Vout
GND
Vbatt
Comm+
Comm-
Present
Handle

302

FIG. 8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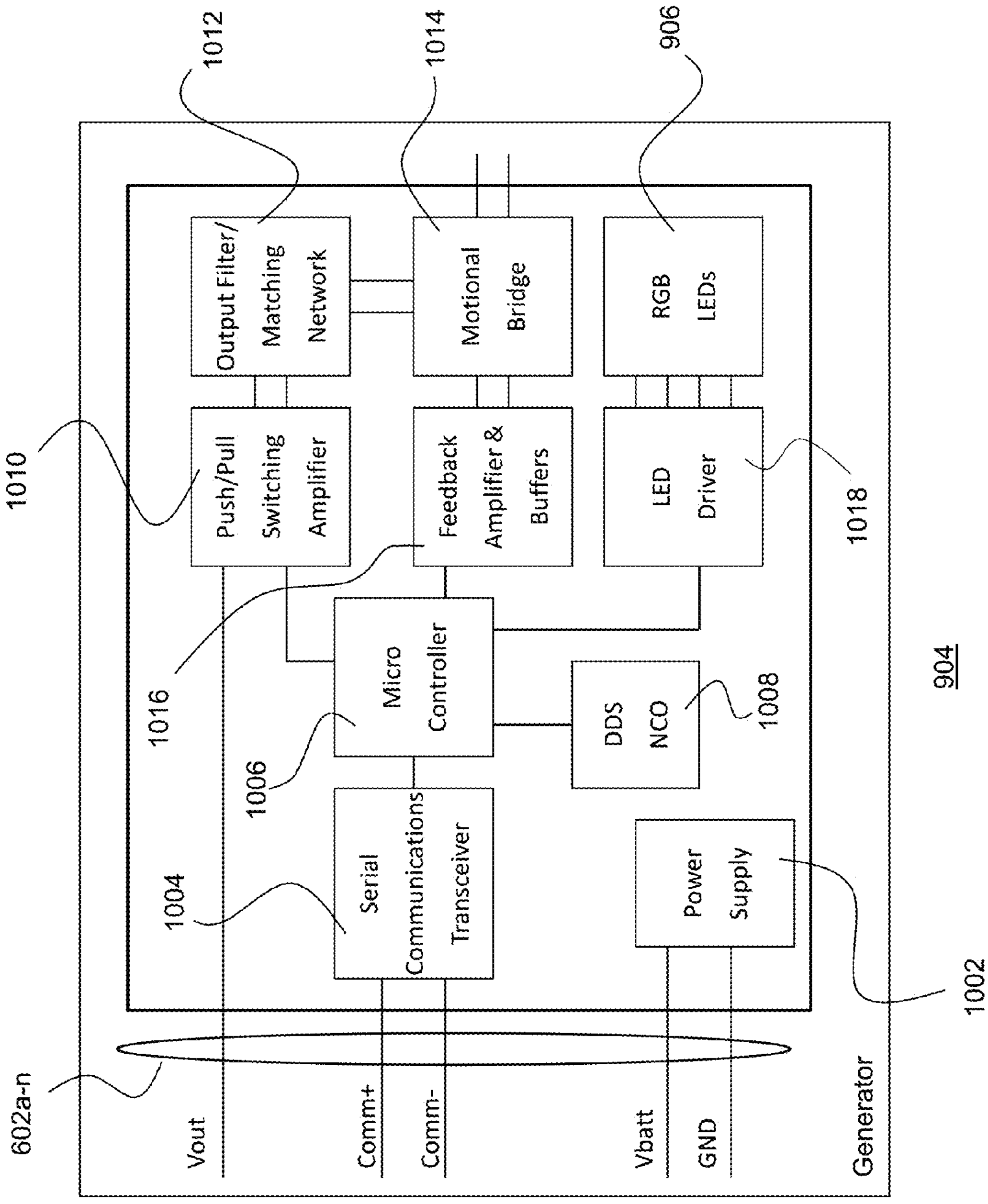
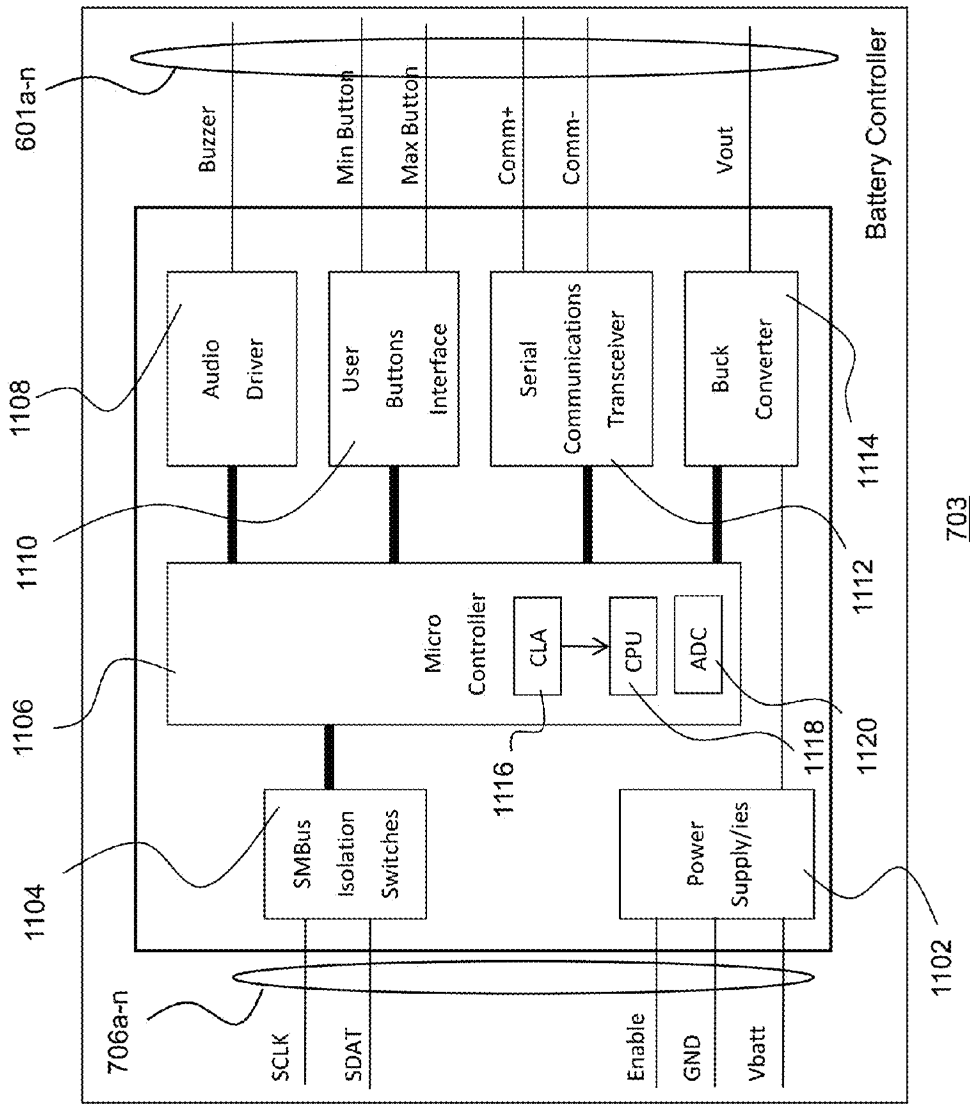
Transducer
904
912
914
906
RGB LEDs
Generator
CLA
CPU
Clk
1006
ADC
916
602a-n
Vout
GND
Vbatt
Comm+
Comm-
908
TAG
303

FIG. 9



1012
1014
906
1010
Output Filter/ Matching Network
Motional Bridge
RGB LEDs
Push/Pull Switching Amplifier
Feedback Amplifier & Buffers
LED Driver
1018
1016
Micro Controller
DDS NCO
1008
1006
Serial Communications Transceiver
1004
Power Supply
1002
602a-n
Vout
Comm+
Comm-
Vbatt
GND
Generator
904

FIG. 10


601a-n
Buzzer
Min Button
Max Button
Comm+
Comm-
Vout
Battery Controller
1108
Audio Driver
User Buttons Interface
Serial Communications Transceiver
Buck Converter
1114
1110
1112
1106
Micro Controller
CLA
CPU
ADC
1116
1118
1120
1104
SMBus Isolation Switches
Power Supply/ies
1102
706a-n
SCLK
SDAT
Enable
GND
Vbatt

703

FIG. 11

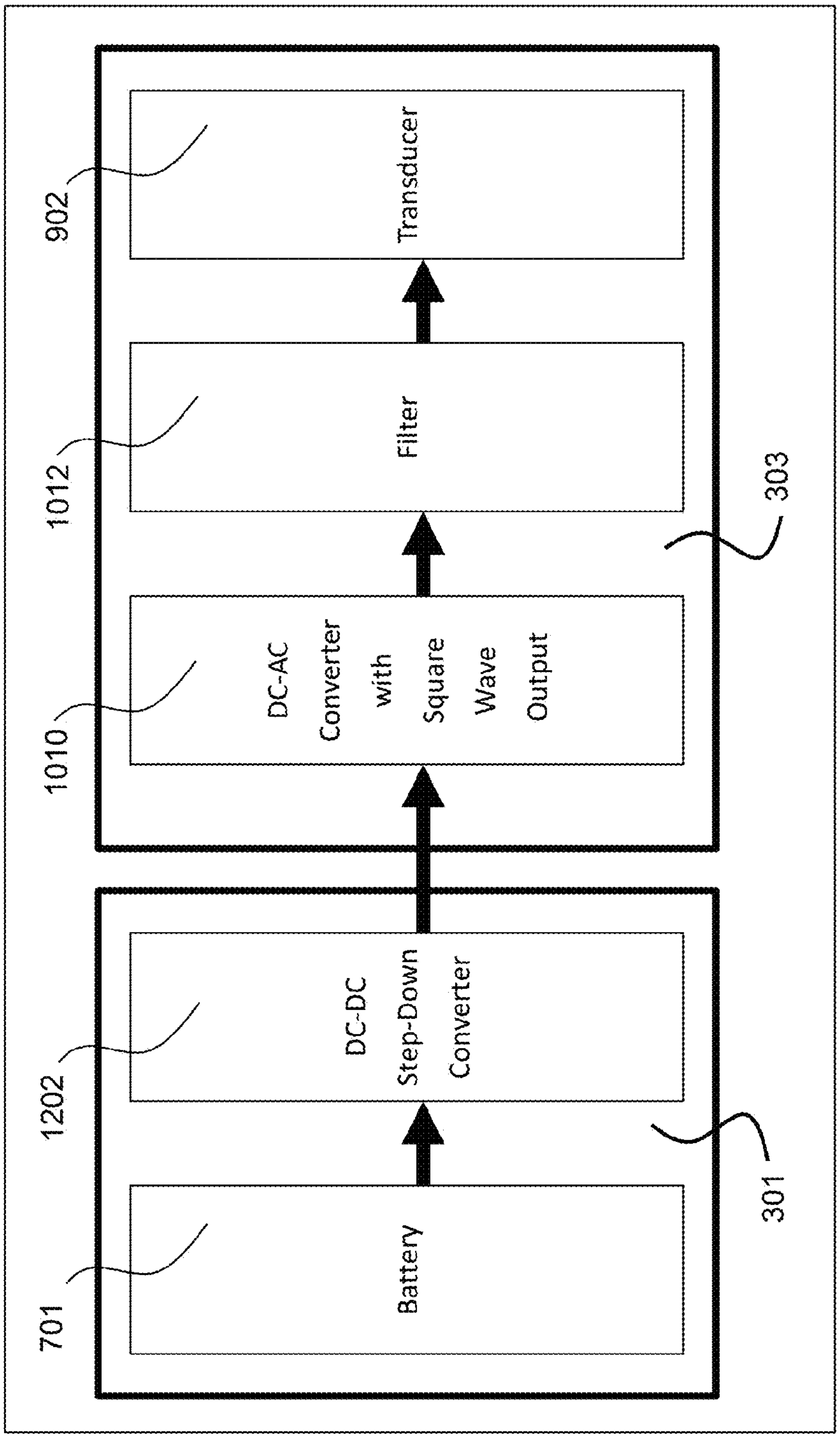

Battery
701
DC-DC Step-Down Converter
1202
301
DC-AC Converter with Square Wave Output
1010
Filter
1012
Transducer
902
303

FIG. 12

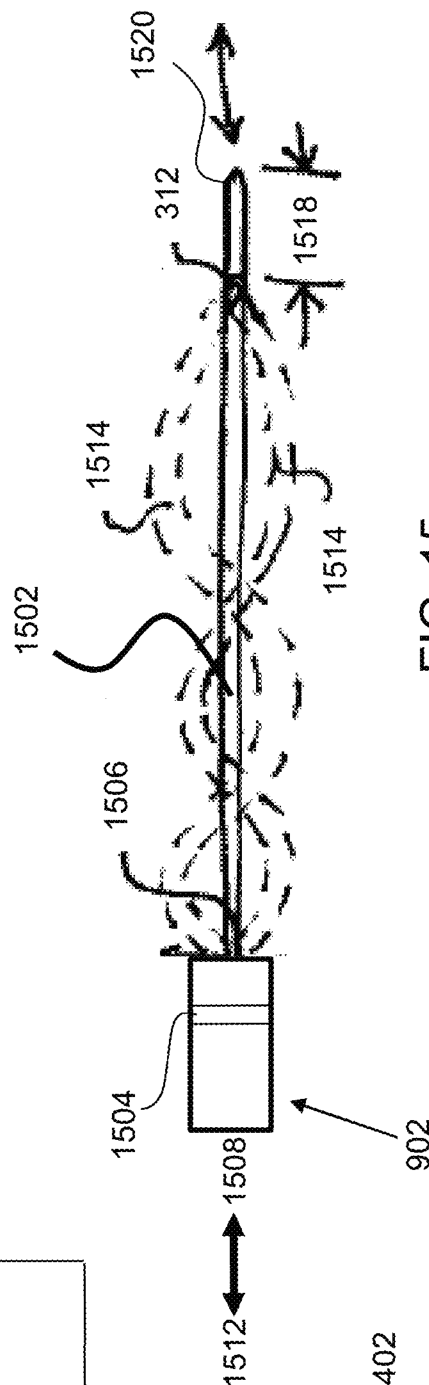


FIG. 15

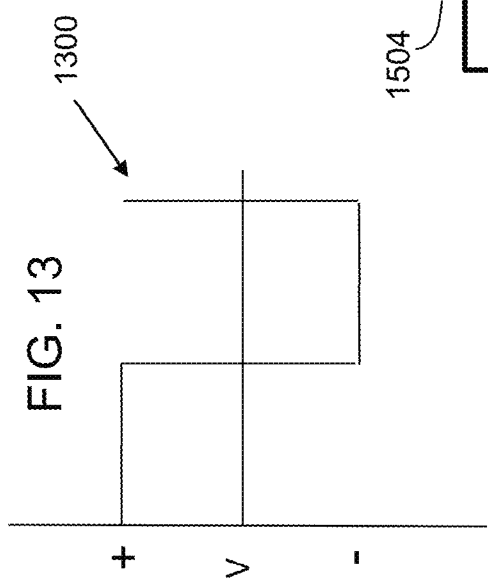


FIG. 13

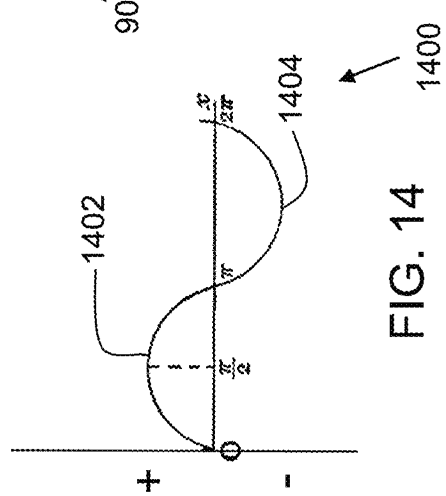
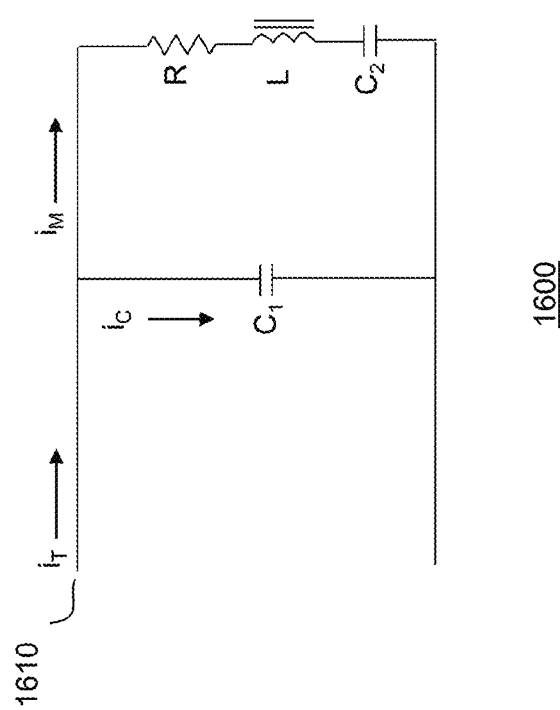
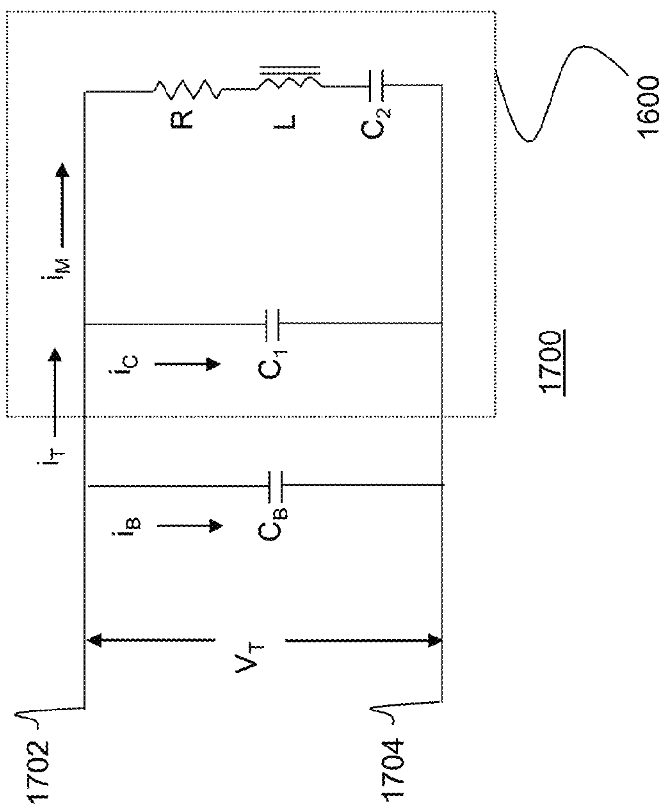


FIG. 14



1610
i_T
i_M
i_C
C_1
R
L
C_2
1600

FIG. 16



1702
1704
V_T
i_B
C_B
i_T
i_C
C_1
i_M
R
L
C_2
1600
1700

FIG. 17

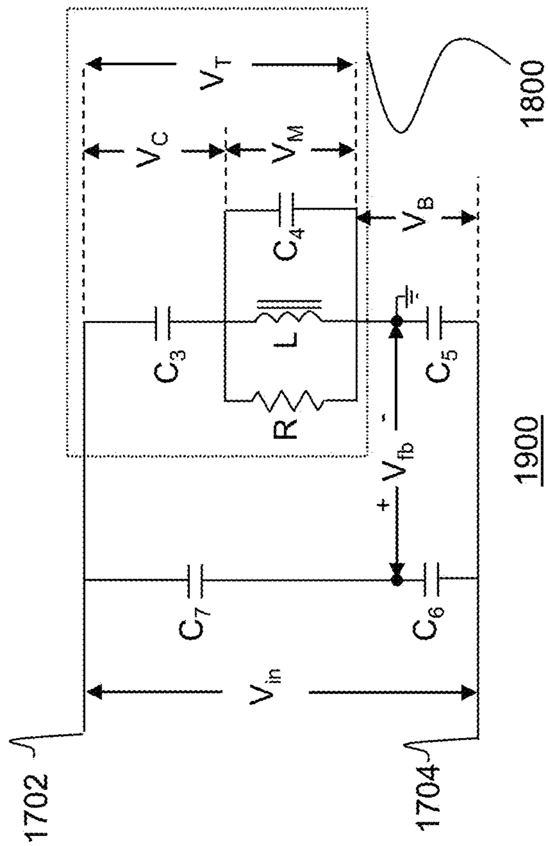

1900
1800
1702
1704
V_T
V_C
V_M
V_B
C_3
C_4
C_5
C_6
C_7
L
R
$+ V_{fb} -$
V_{in}

FIG. 19

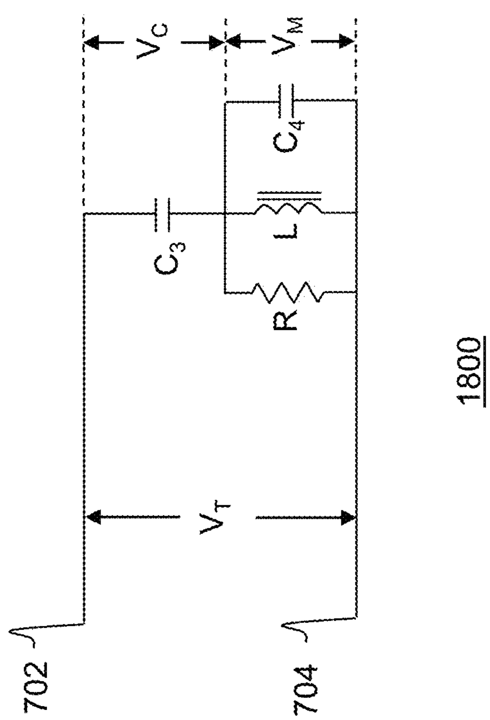

1800
1702
1704
V_C
V_M
V_T
C_3
C_4
L
R

FIG. 18

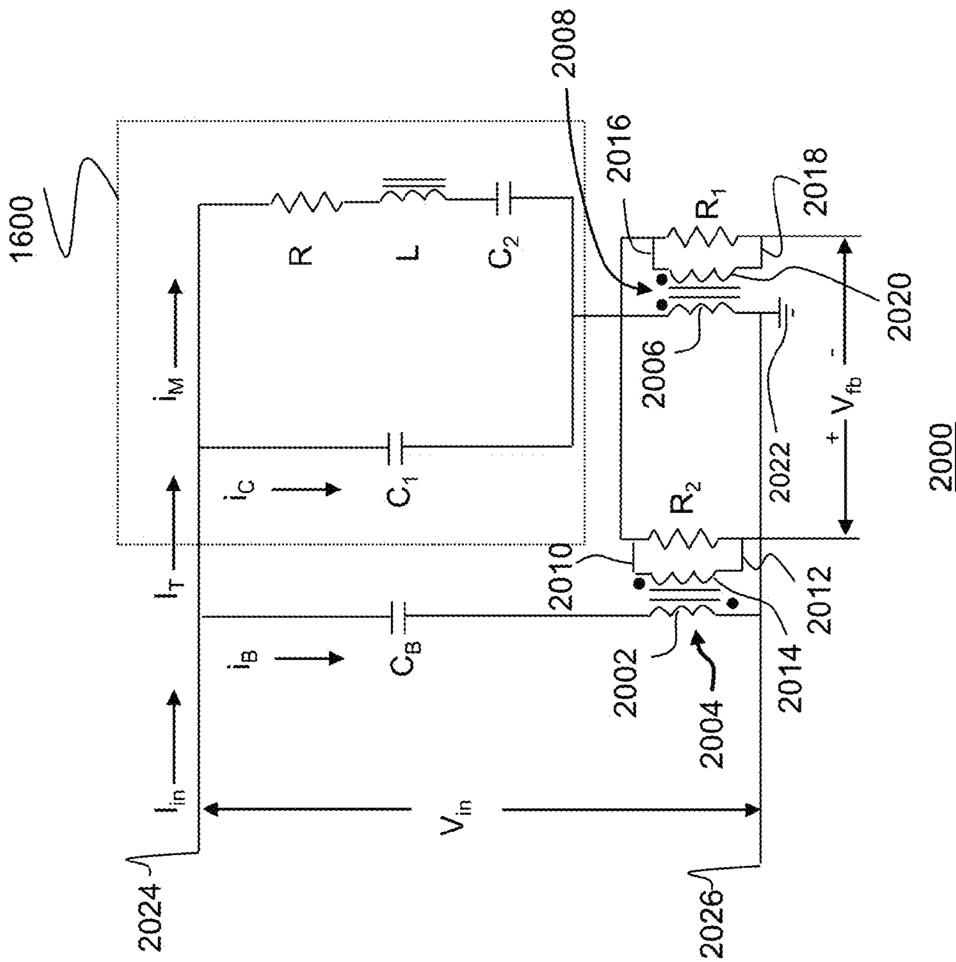
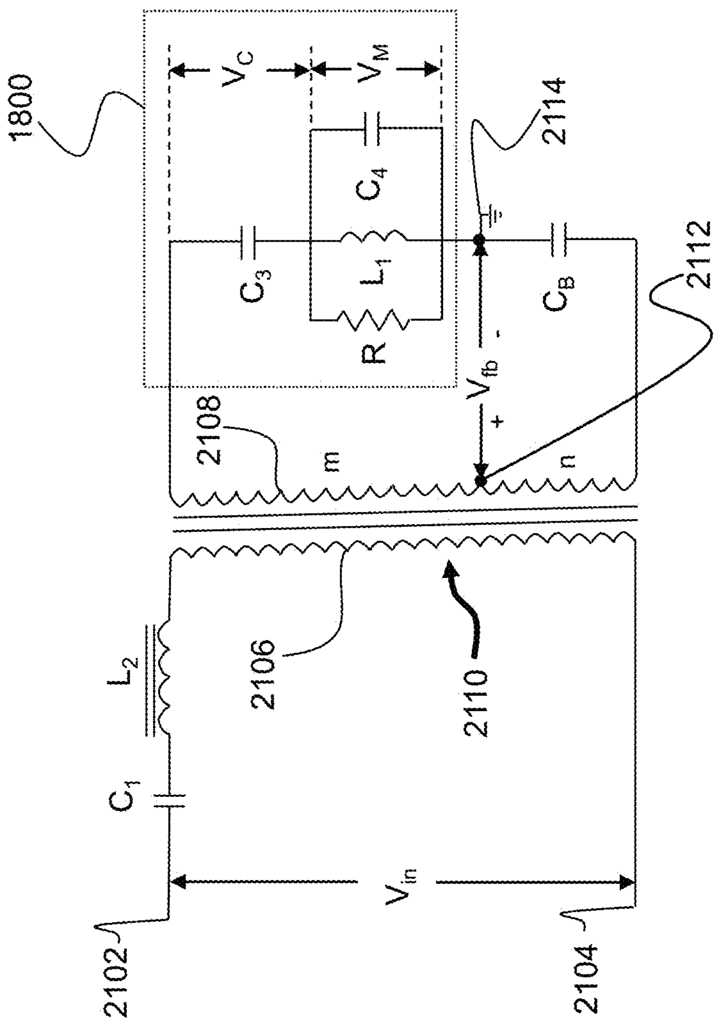
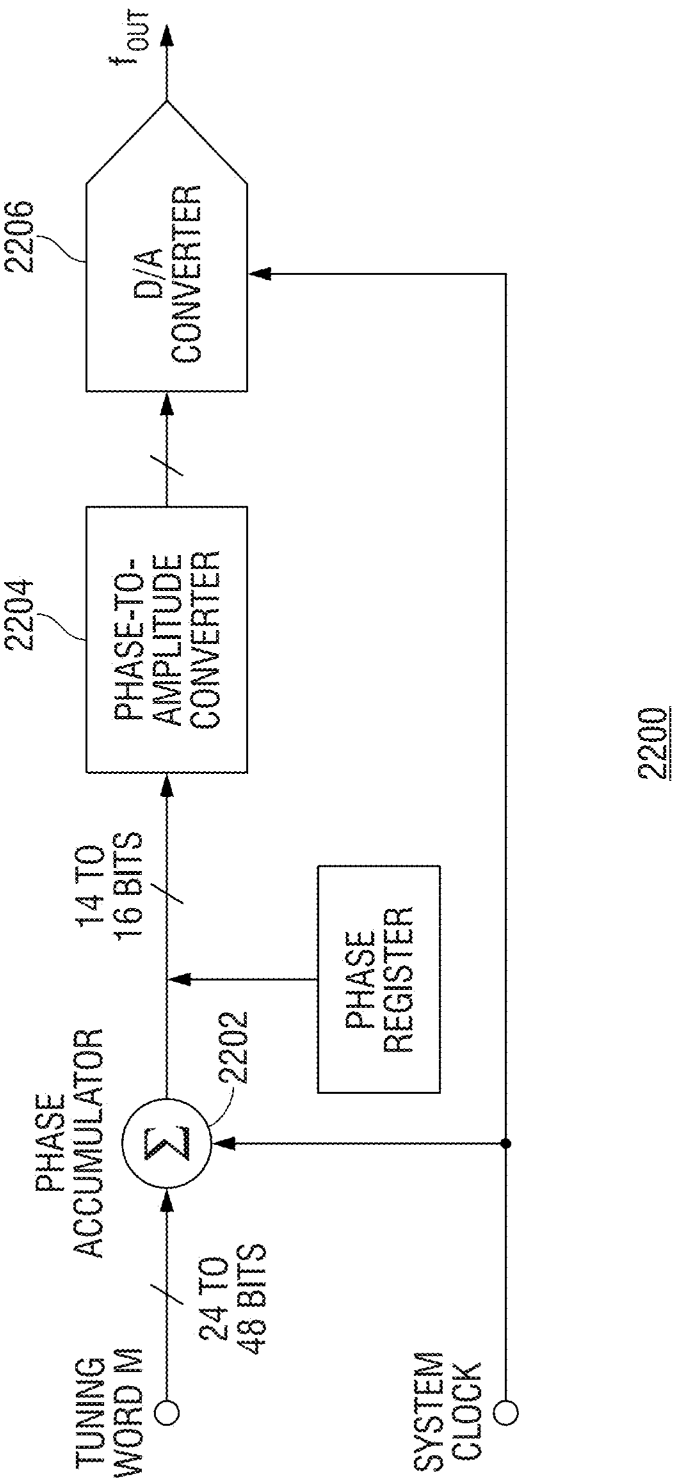

1600
R
L
C_2
i_M
i_C
C_1
I_T
i_B
C_B
I_{in}
V_{in}
2024
2026
2008
2016
R_1
2018
2020
2006
2022
$+ V_{fb} -$
2000
R_2
2010
2012
2014
2002
2004

FIG. 20


1800
V_C
V_M
2114
C_4
C_3
L_1
R
C_B
2112
V_{fb}
2108
m
n
2106
L_2
2110
C_1
V_{in}
2102
2104

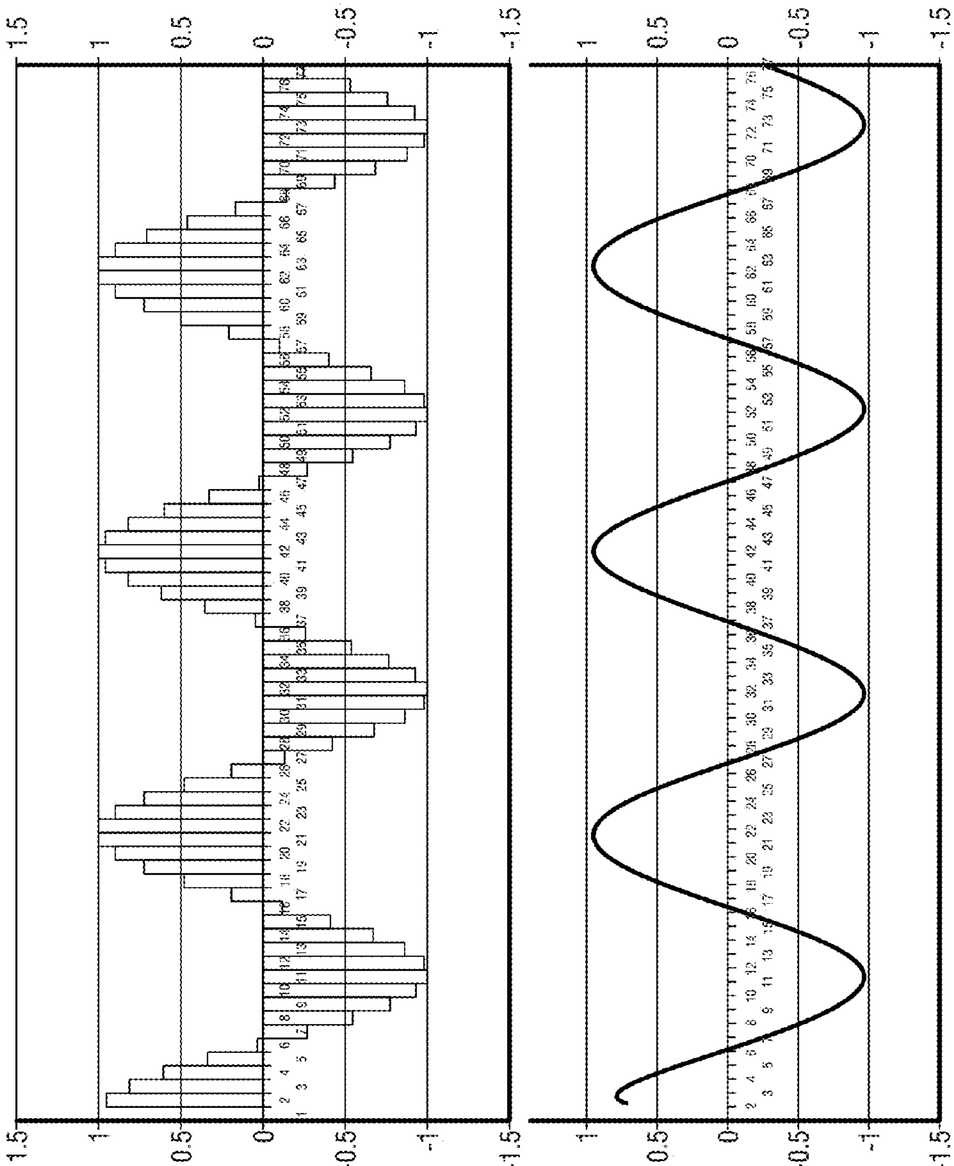
2100

FIG. 21



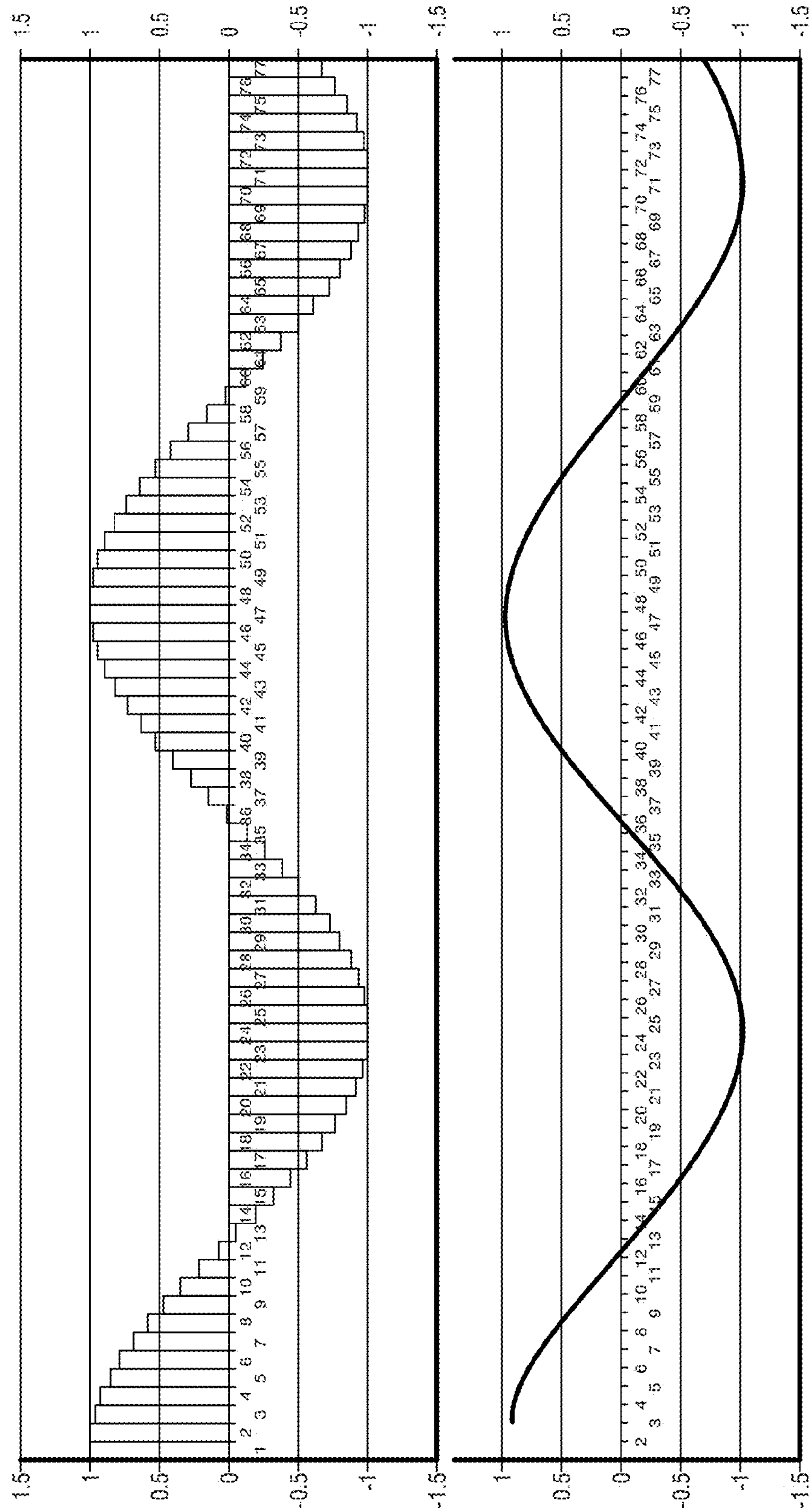
TUNING WORD M
24 TO 48 BITS
PHASE ACCUMULATOR
Σ
2202
PHASE REGISTER
14 TO 16 BITS
PHASE-TO-AMPLITUDE CONVERTER
2204
D/A CONVERTER
2206
f_{OUT}
SYSTEM CLOCK
2200

FIG. 22



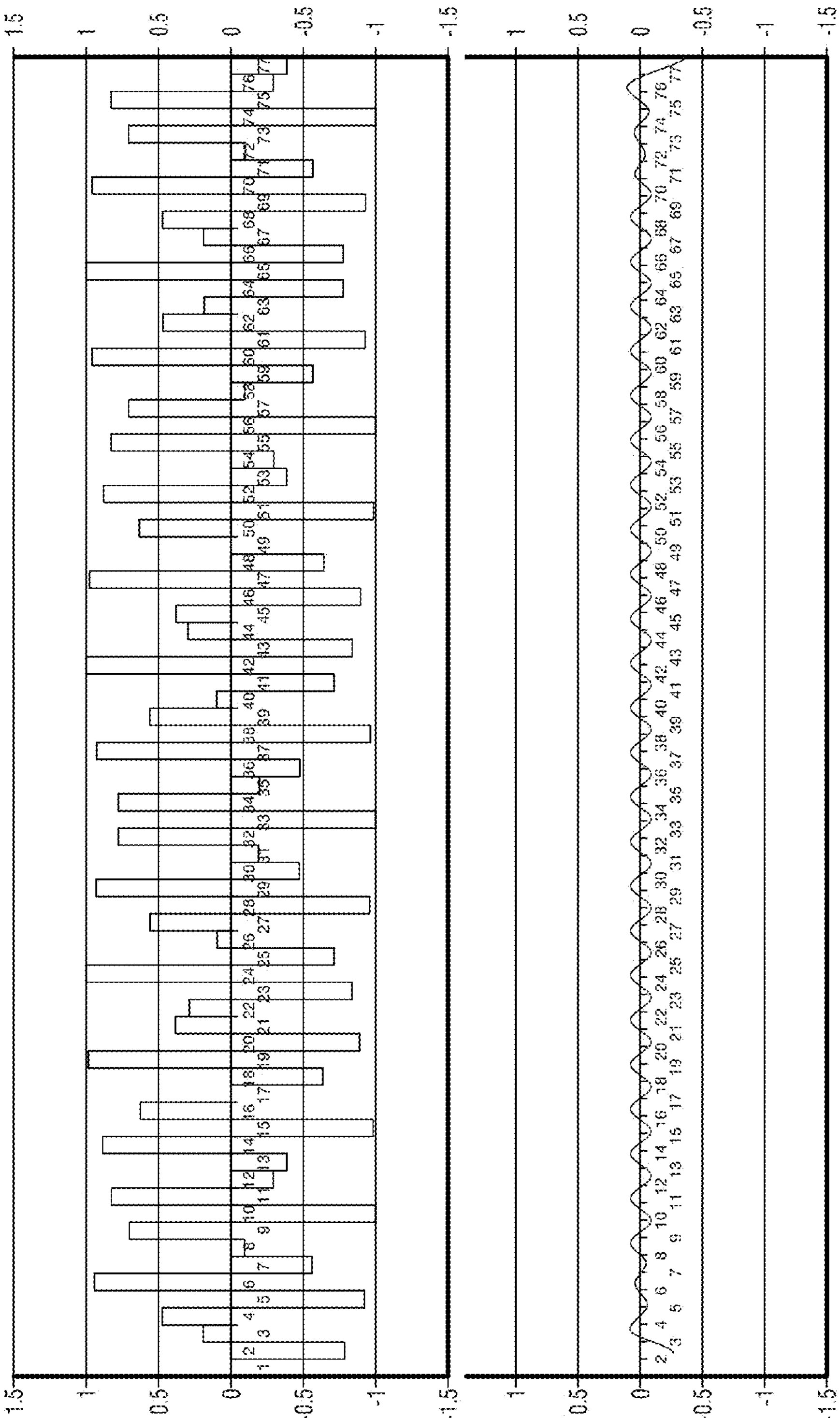
2300

FIG. 23



2400

FIG. 24



2500

FIG. 25

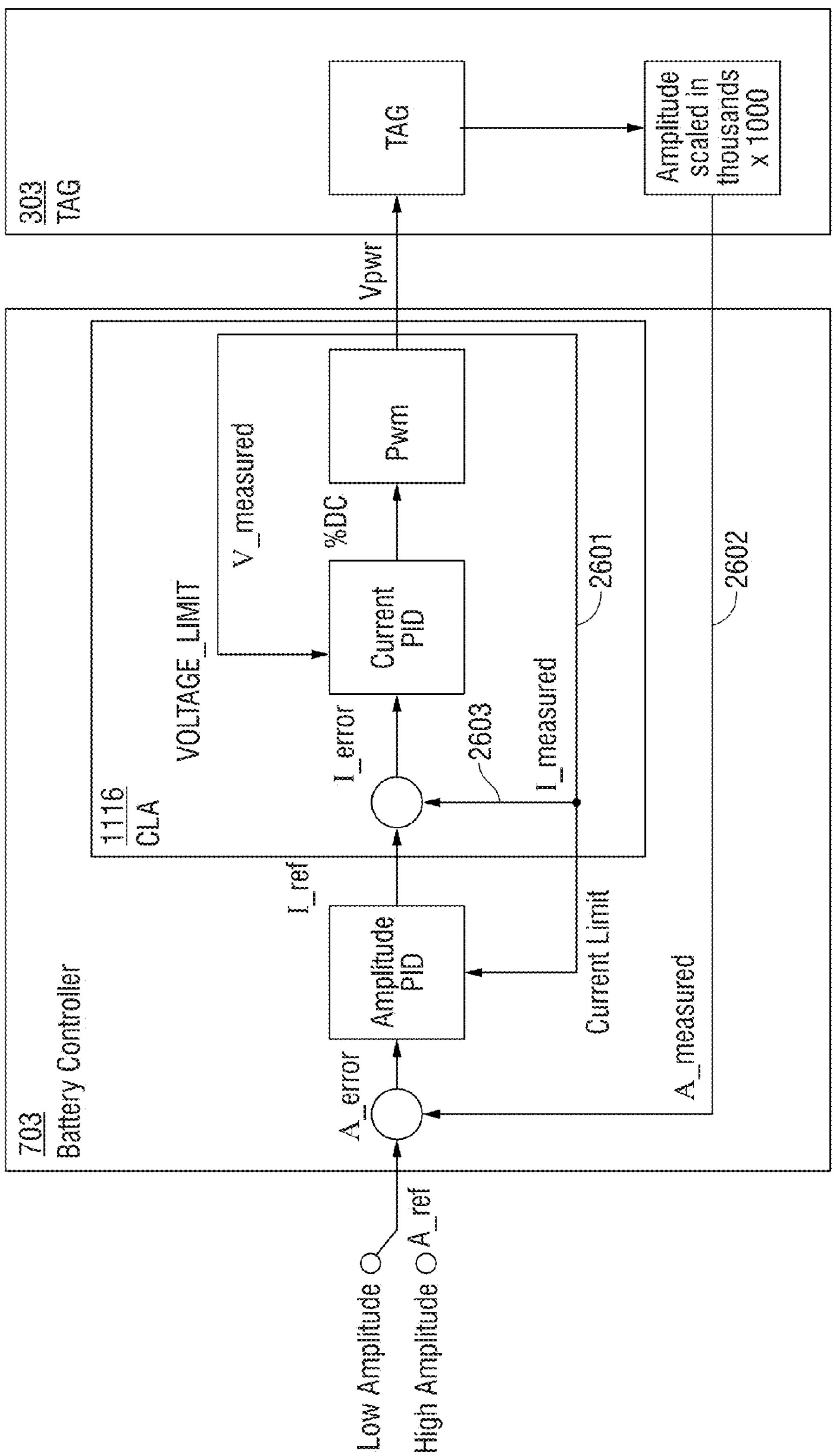

303
TAG
TAG
Amplitude scaled in thousands x 1000
Vpwr
703
Battery Controller
1116
CLA
VOLTAGE_LIMIT
V_measured
Pwm
%DC
Current PID
2601
2602
2603
I_error
I_measured
I_ref
Amplitude PID
Current Limit
A_measured
A_error
A_ref
Low Amplitude
High Amplitude

FIG. 26

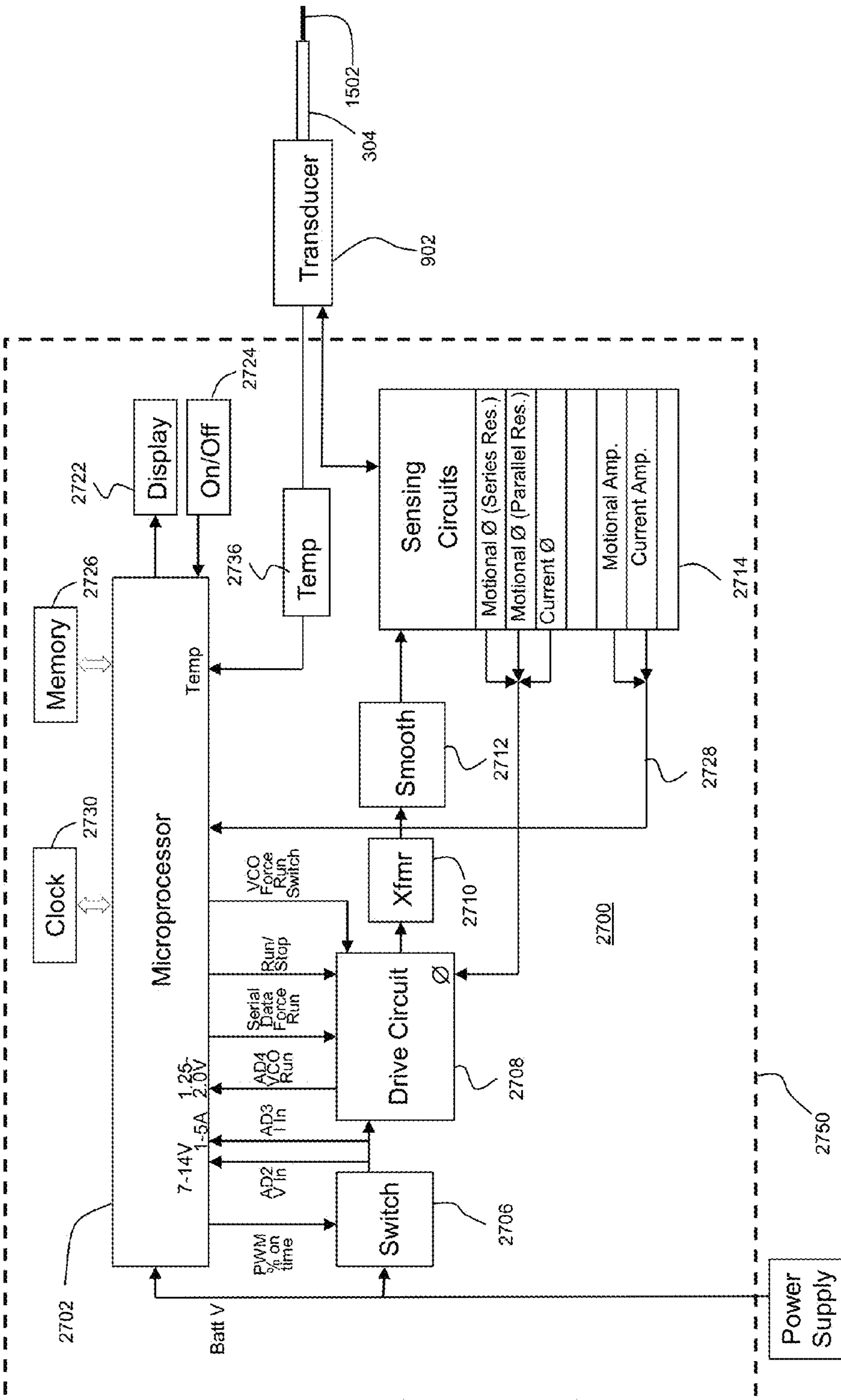

1502
304
Transducer
902
2724
Display
On/Off
2722
Temp
2736
Sensing Circuits
Motional Ø (Series Res.)
Motional Ø (Parallel Res.)
Current Ø
Motional Amp.
Current Amp.
2714
Memory
2726
Temp
Smooth
2712
2728
Clock
2730
Microprocessor
VCO Force Run Switch
Xfmr
2710
2700
Run/Stop
Serial Data Force Run
Drive Circuit
Ø
2708
AD4 VCO Run
1.25-2.0V
AD3 I In
1-5A
7-14V
AD2 V In
2750
Switch
2706
PWM % on time
2702
Batt V
Power Supply
2704

FIG. 27

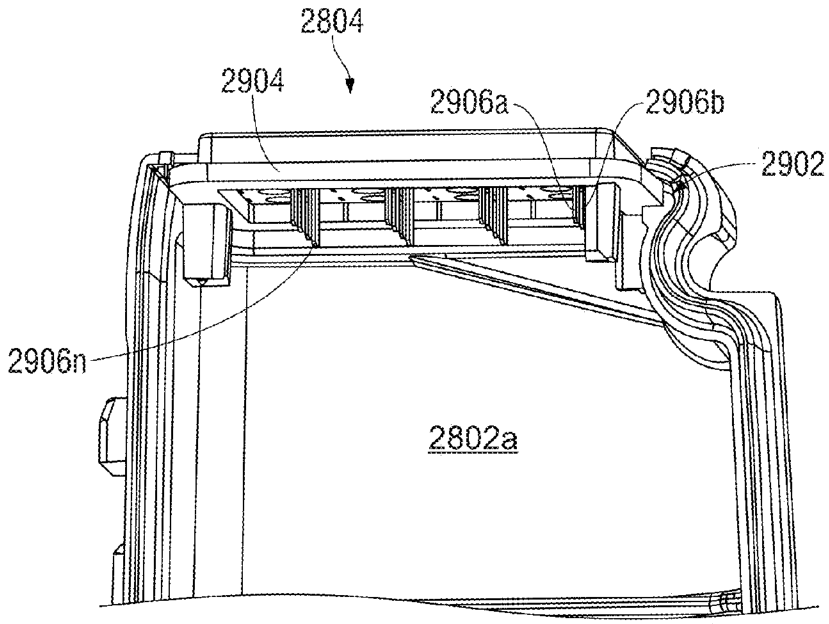

2804
2904
2906a
2906b
2902
2906n
2802a

FIG. 29

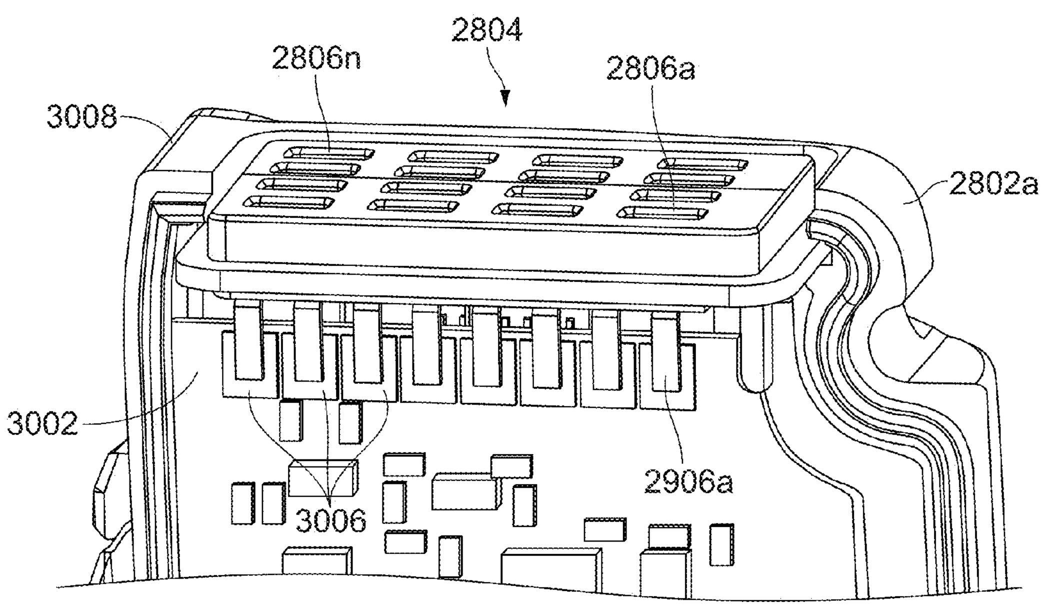

2804
2806n
2806a
3008
2802a
3002
2906a
3006

FIG. 30

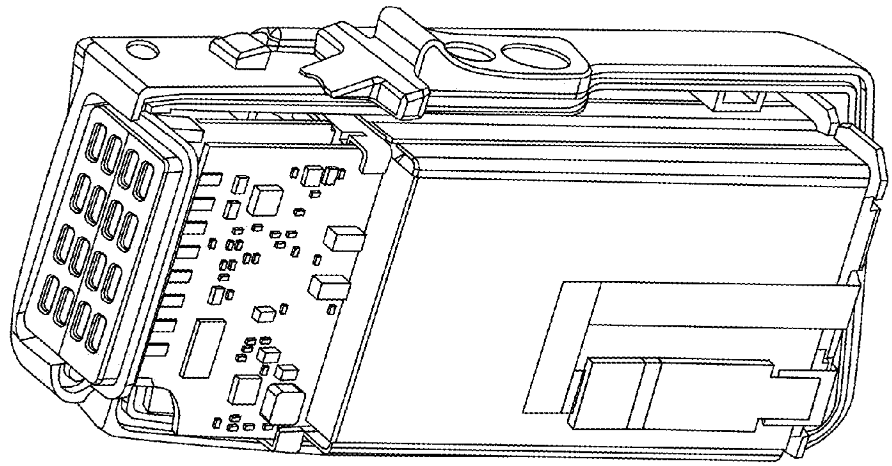


FIG. 32

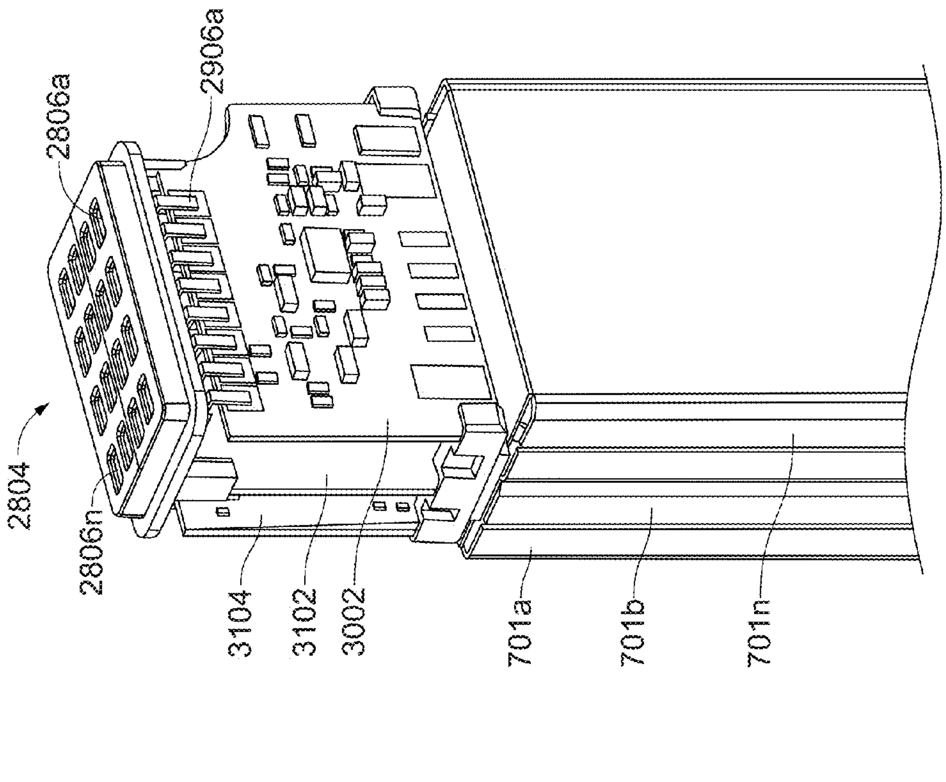


FIG. 31

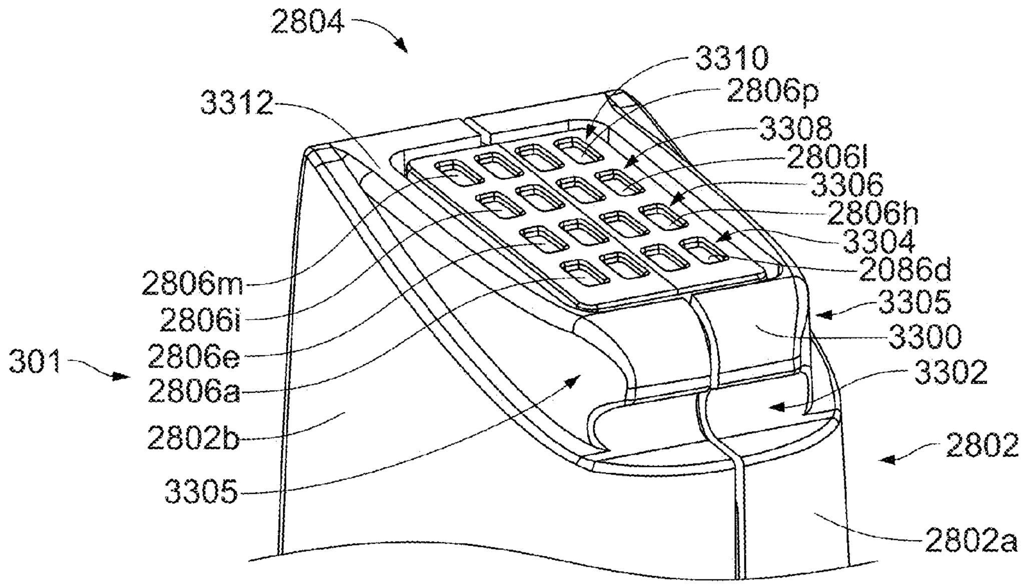

2804
3310
3312
2806p
3308
2806l
3306
2806h
3304
2086d
2806m
2806i
2806e
2806a
3305
3300
3302
301
2802b
2802
3305
2802a

FIG. 33

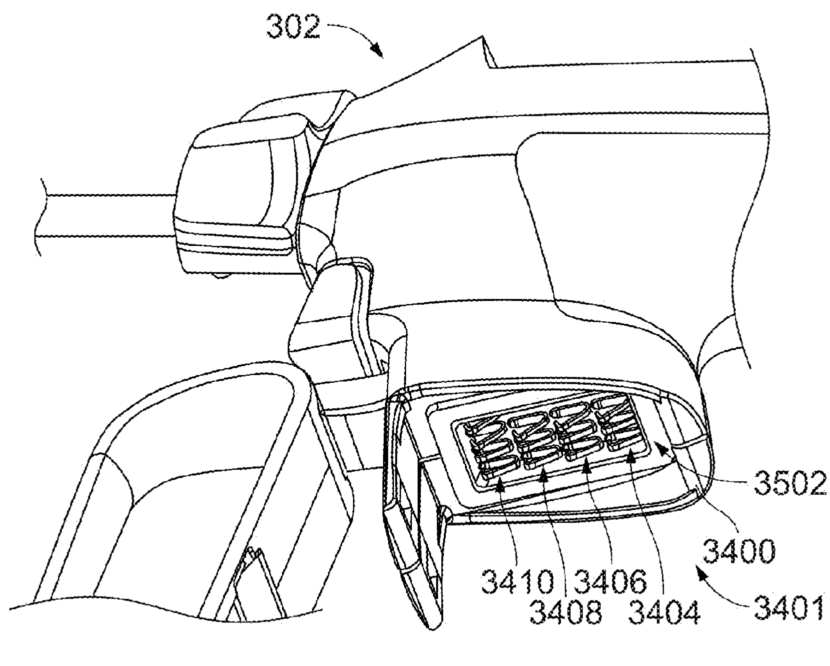

302
3502
3400
3410
3406
3408
3404
3401

FIG. 34

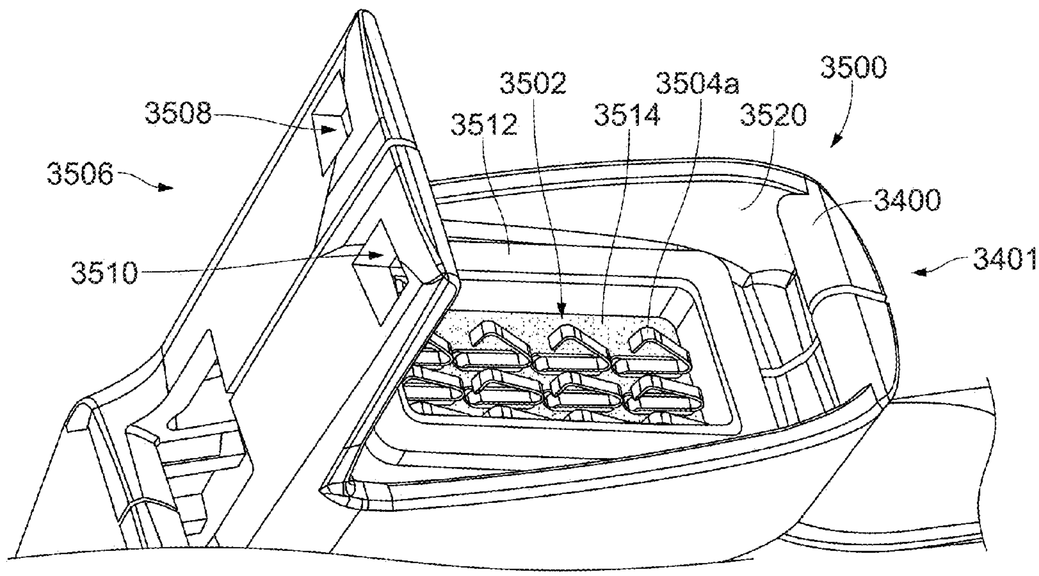

3502
3504a
3500
3508
3512
3514
3520
3506
3400
3510
3401

FIG. 35

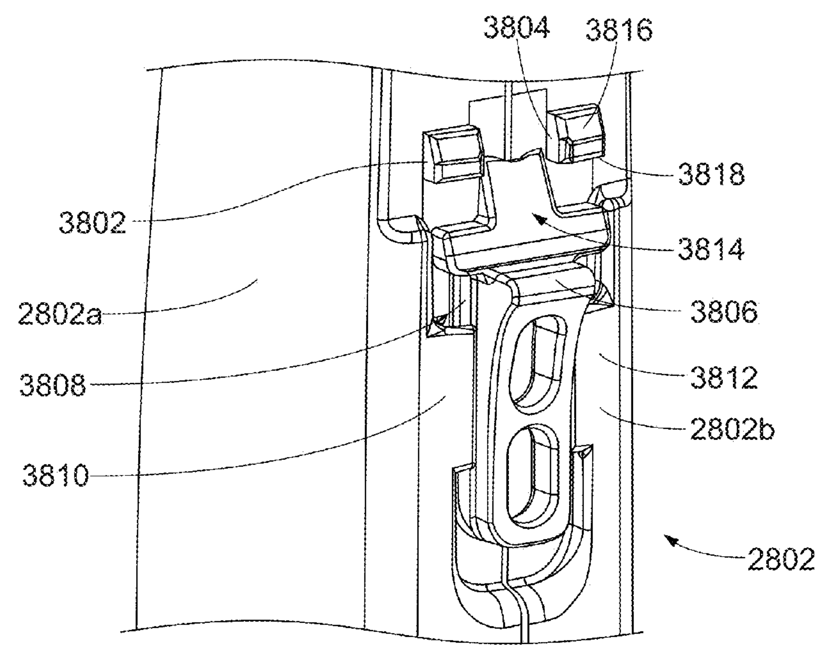

3804
3816
3818
3802
3814
2802a
3806
3808
3812
2802b
3810
2802

FIG. 38

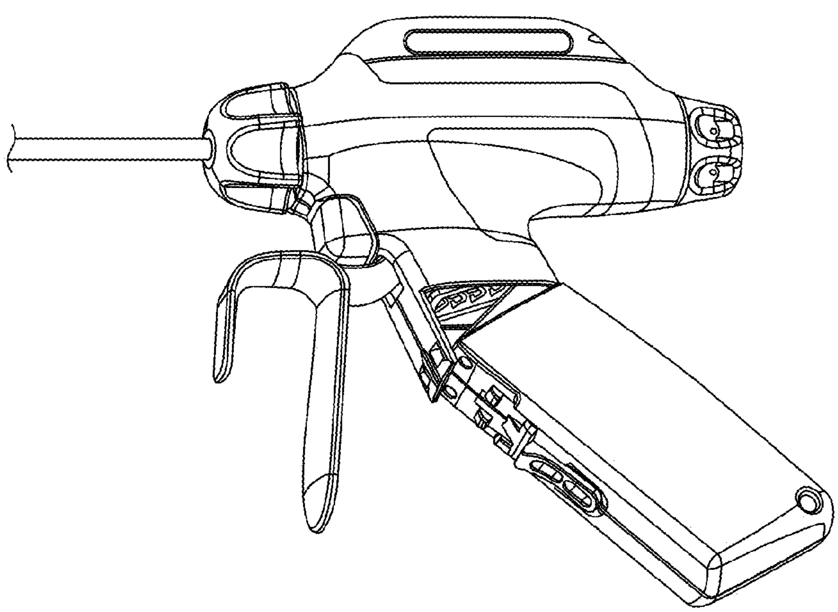


FIG. 36

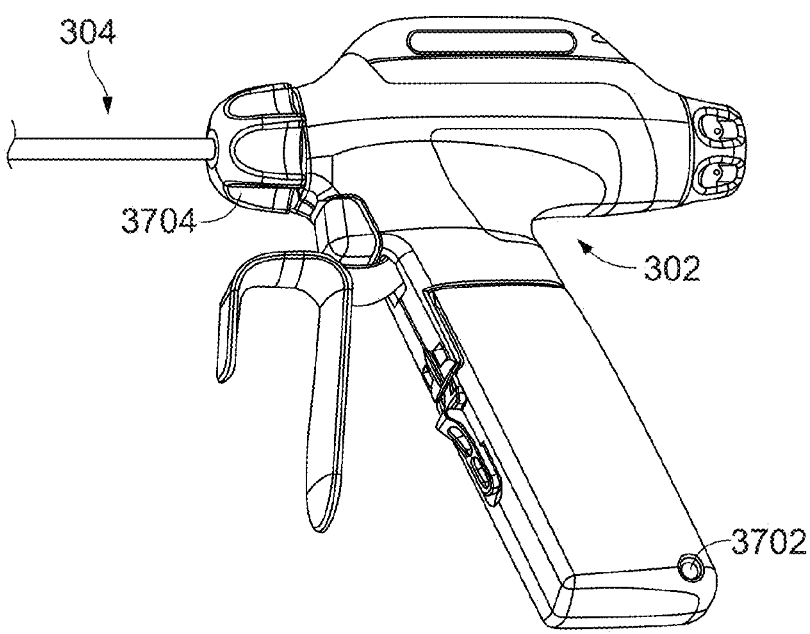


FIG. 37

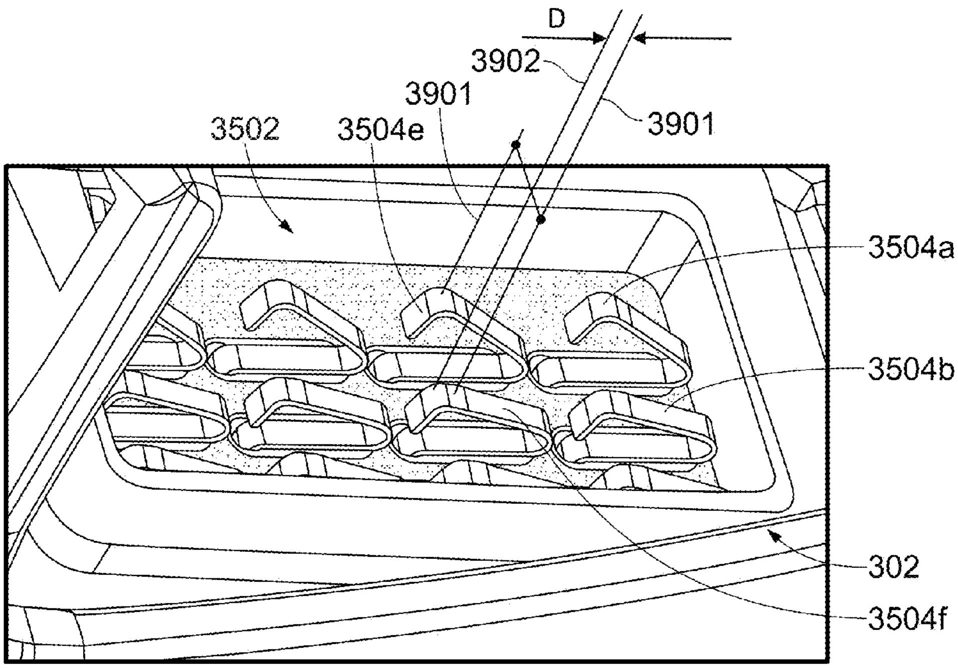


FIG. 39

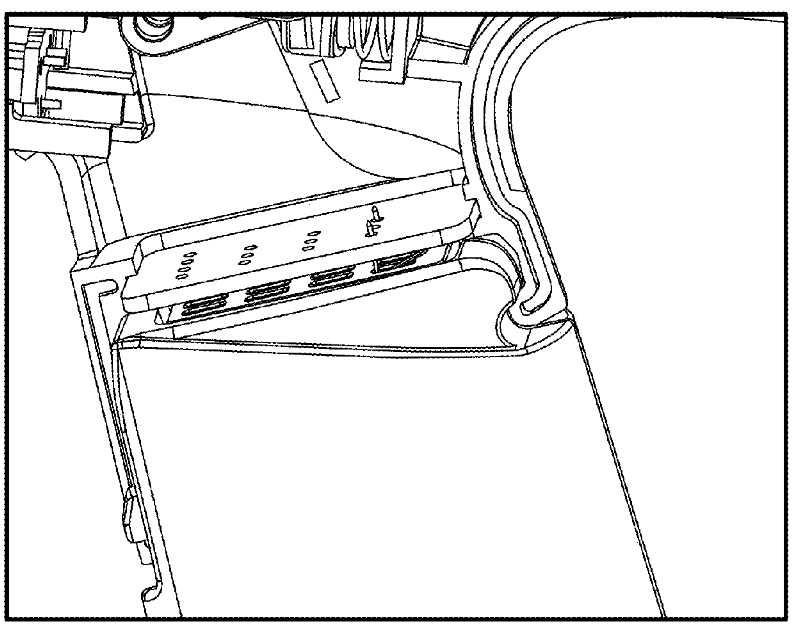


FIG. 40

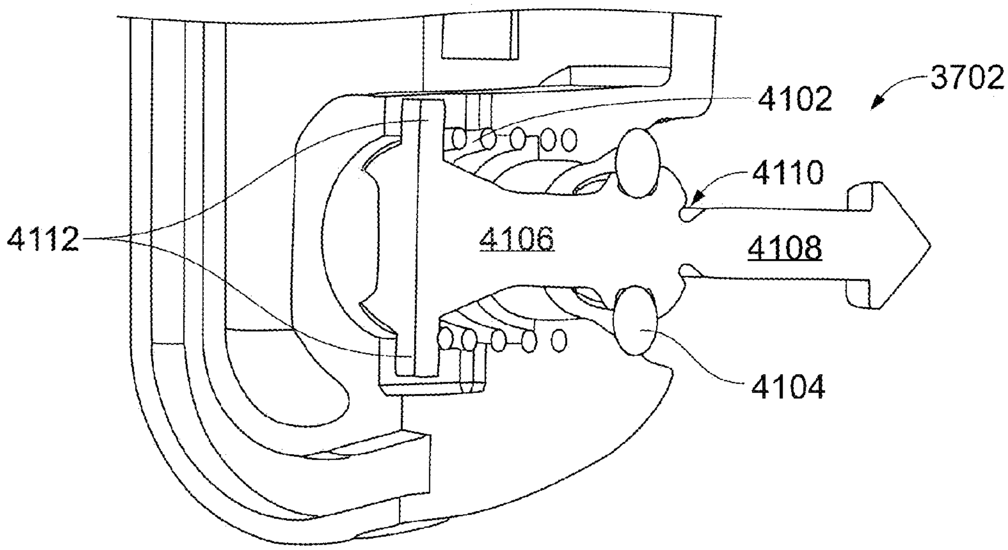

3702
4102
4110
4112
4106
4108
4104

FIG. 41

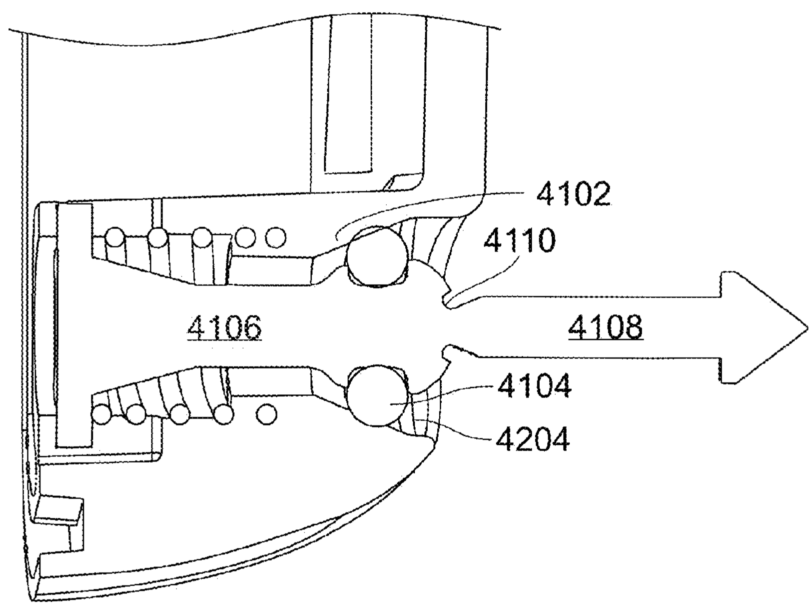

4102
4110
4106
4108
4104
4204

FIG. 42

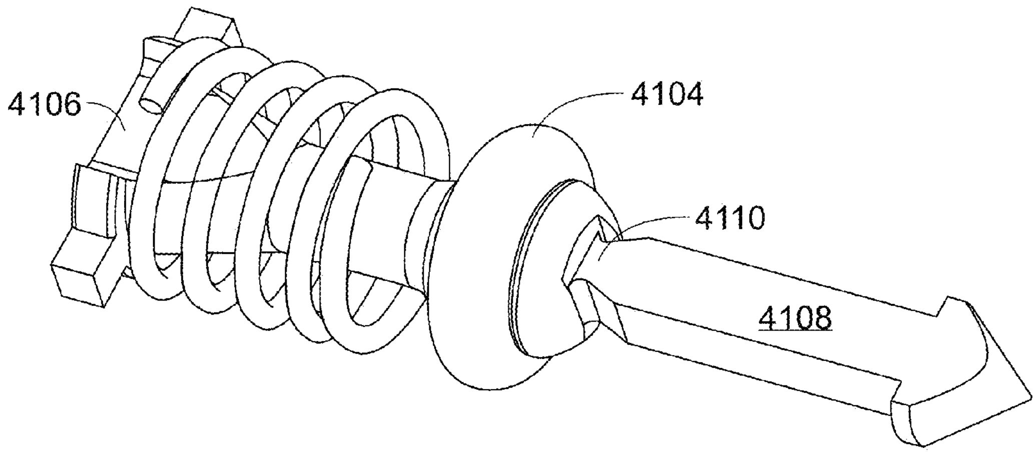


FIG. 43

Chart showing check valve opening event stages
X-axis is pressure
Y-axis is Flow

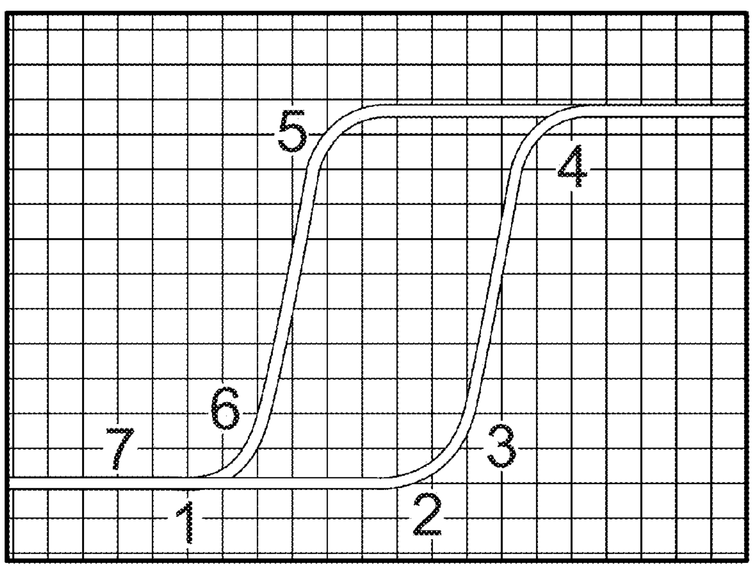


FIG. 44

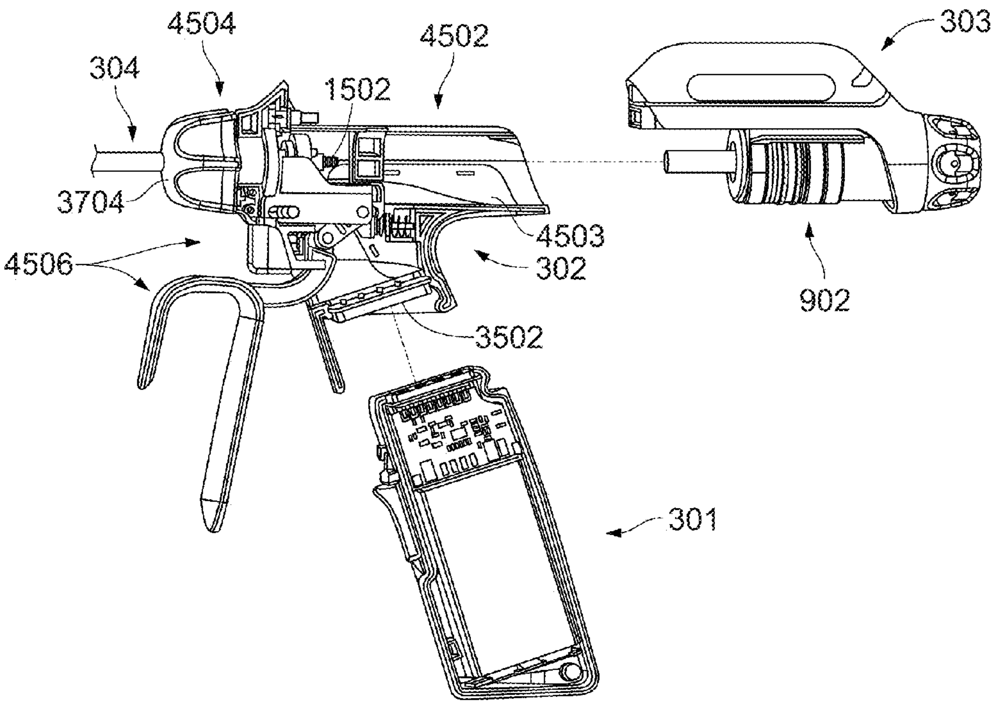

304
4504
4502
1502
303
3704
4503
4506
302
902
3502
301

FIG. 45

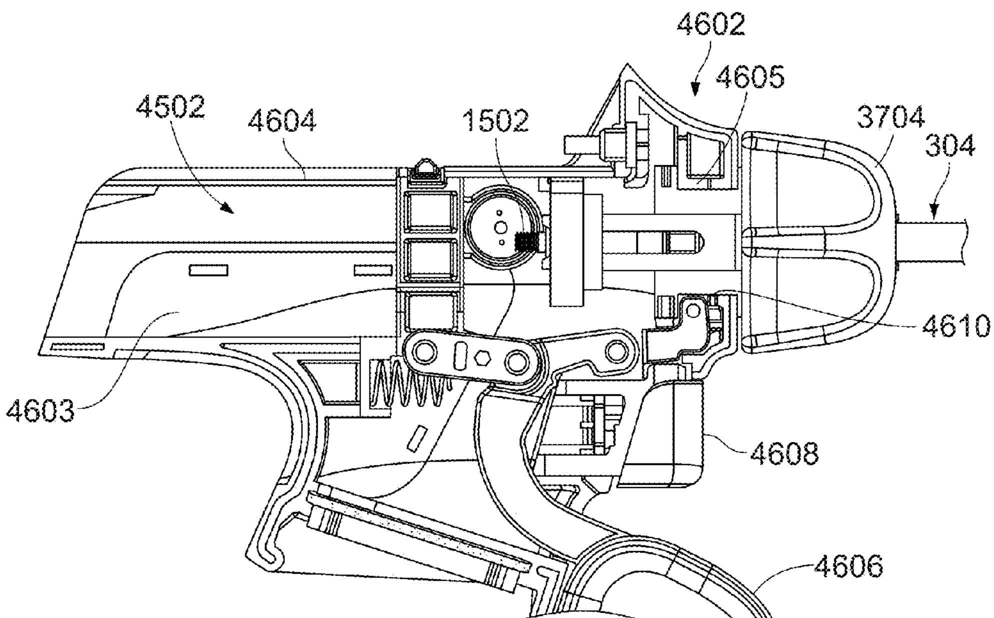

4602
4605
4502
4604
1502
3704
304
4610
4603
4608
4606

FIG. 46

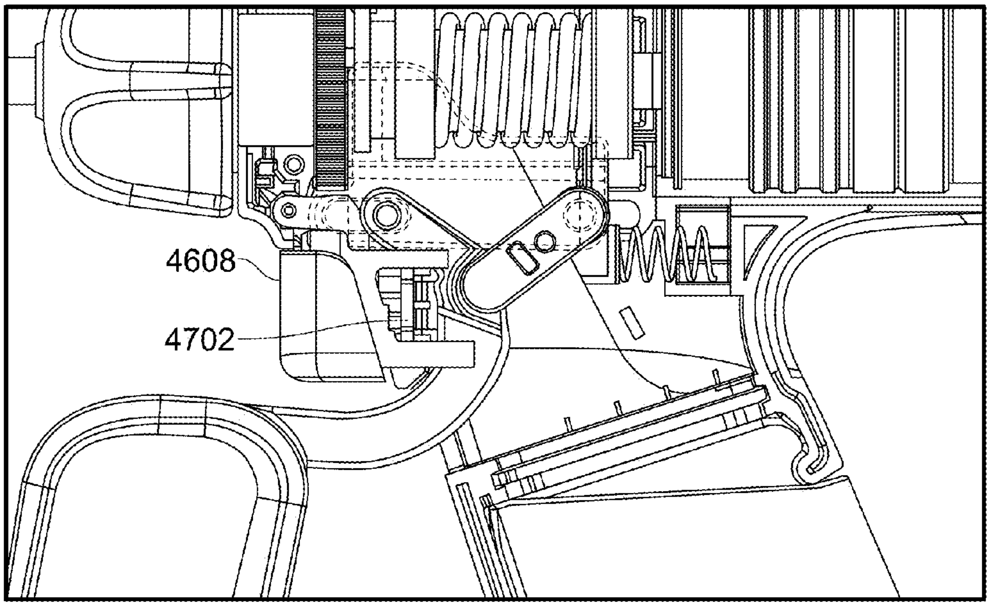


FIG. 47

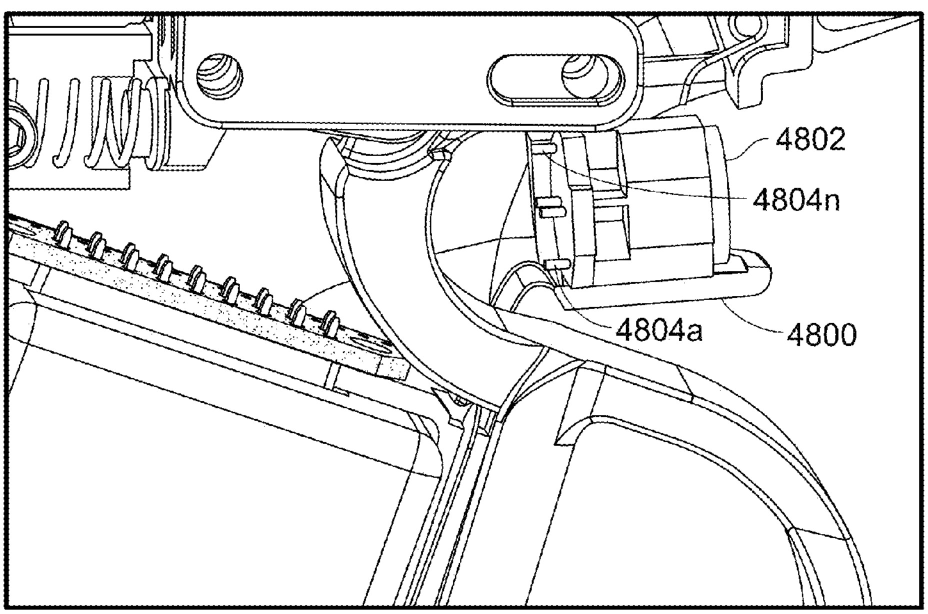


FIG. 48

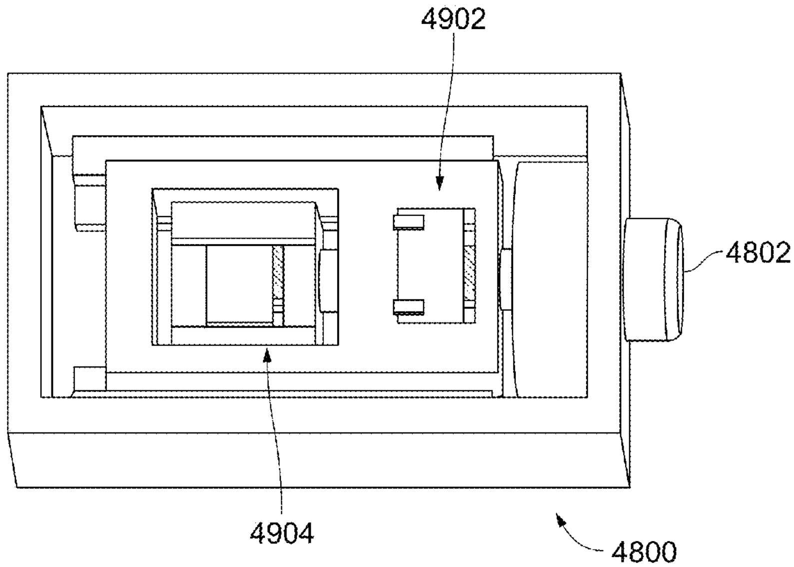

4902
4802
4904
4800

FIG. 49

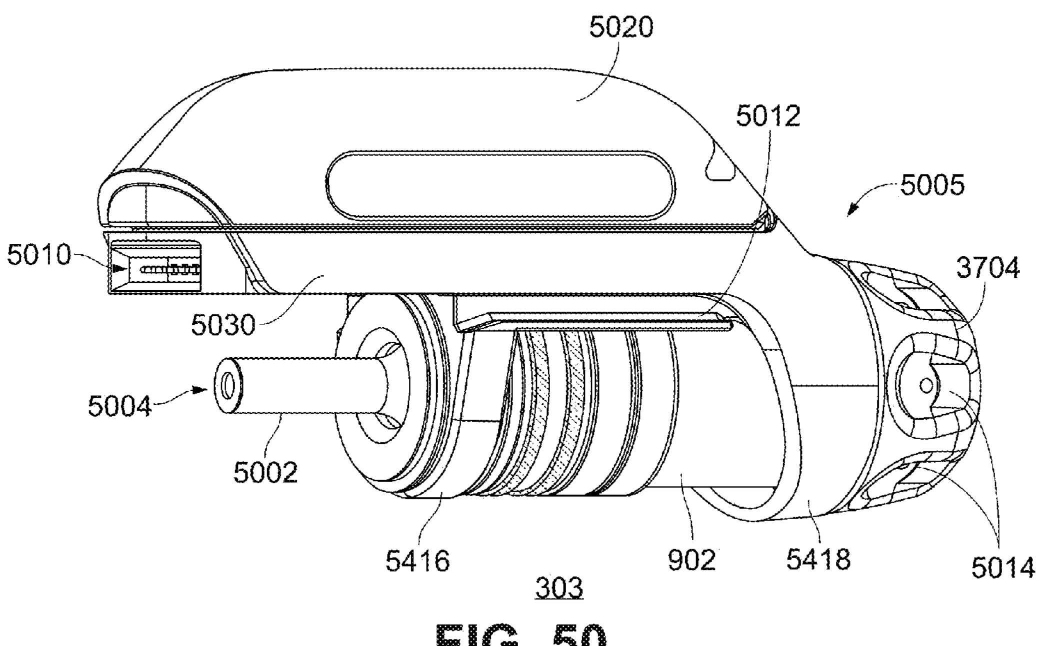

5020
5012
5005
5010
3704
5030
5004
5002
5416
902
5418
5014
303

FIG. 50

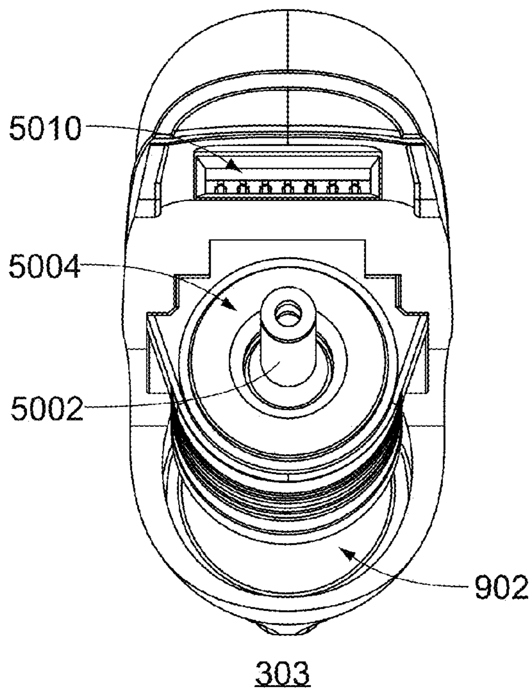


FIG. 51

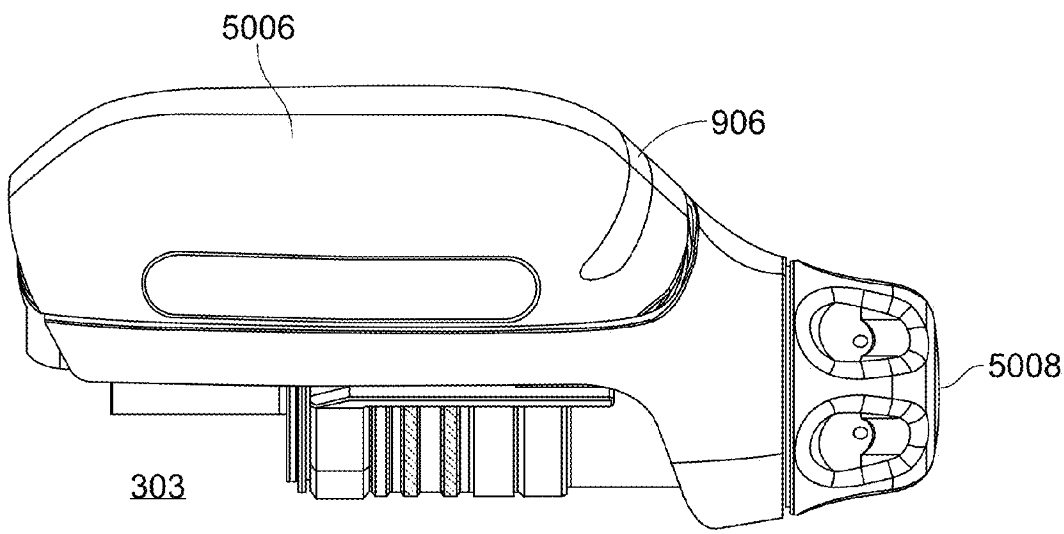


FIG. 52

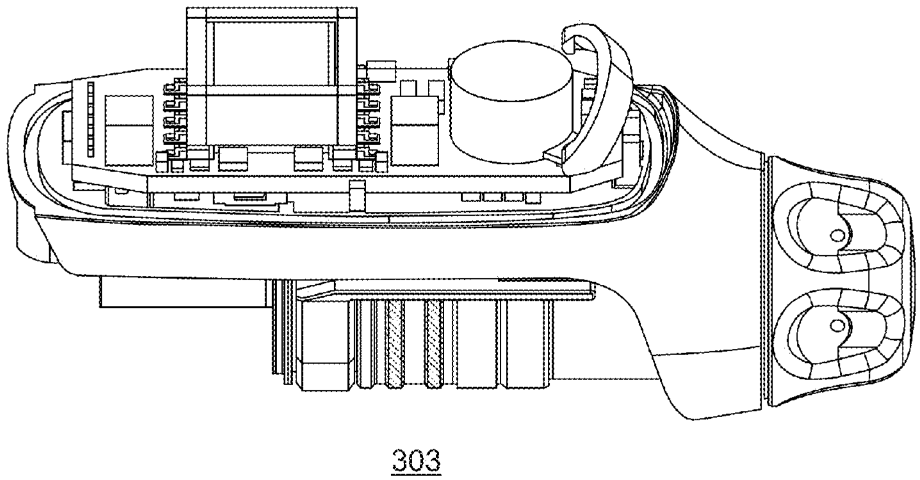

303

FIG. 53

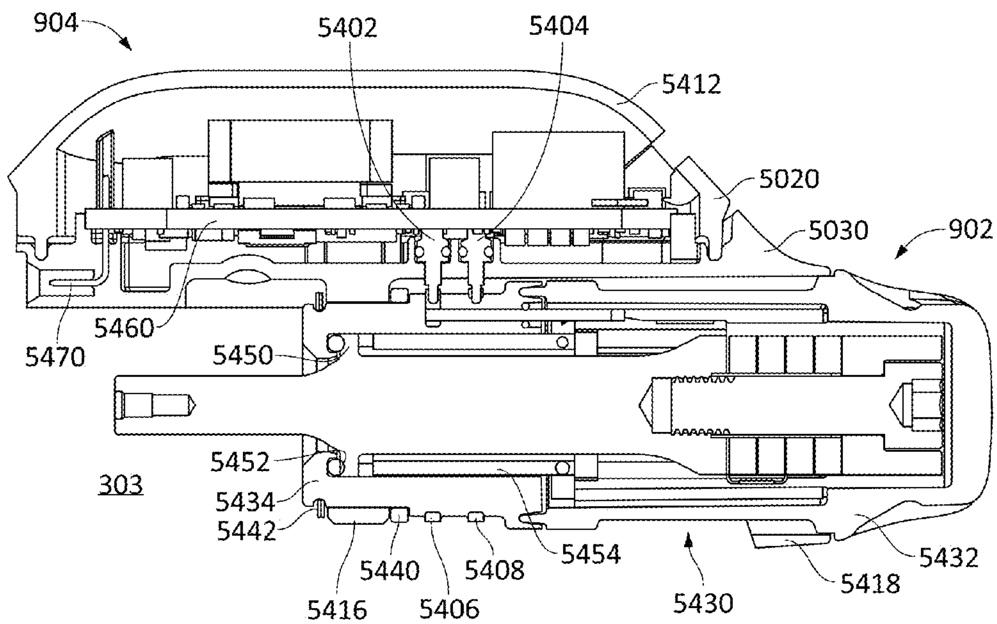

904
5402
5404
5412
5020
5030
902
5460
5470
5450
5452
303
5434
5442
5440
5408
5454
5416
5406
5430
5418
5432

FIG. 54

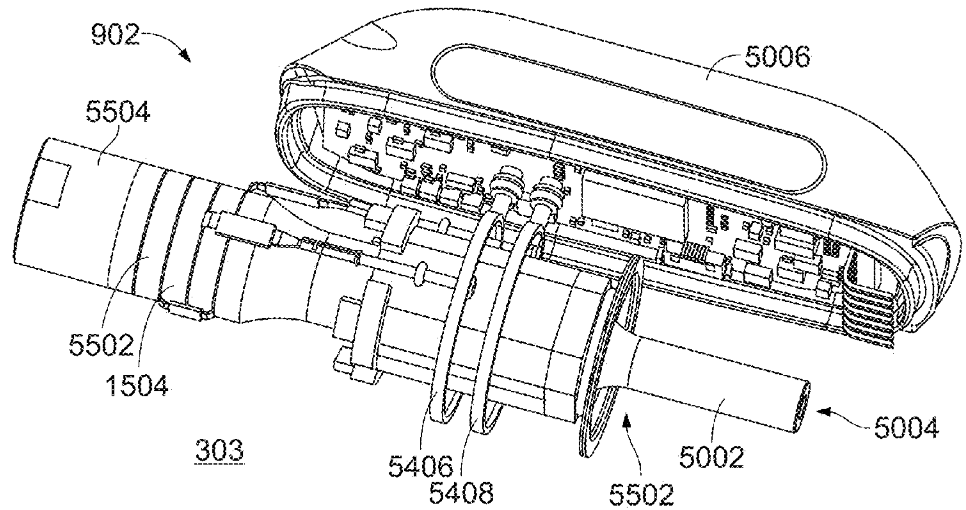

902
5006
5504
5502
1504
303
5406
5408
5502
5002
5004

FIG. 55

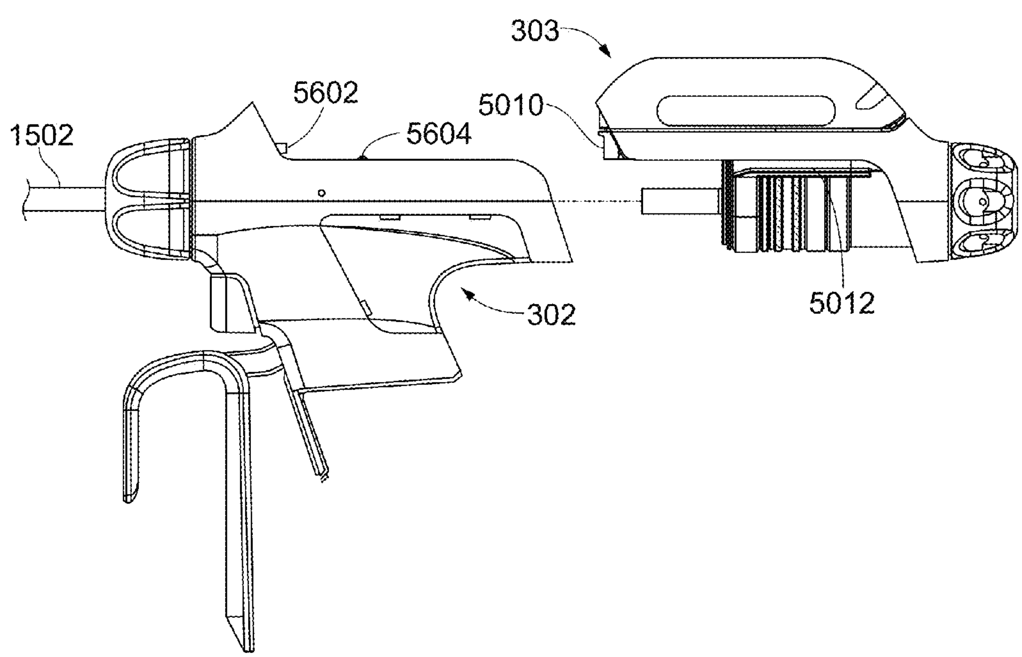

303
5602
5010
5604
1502
302
5012

FIG. 56

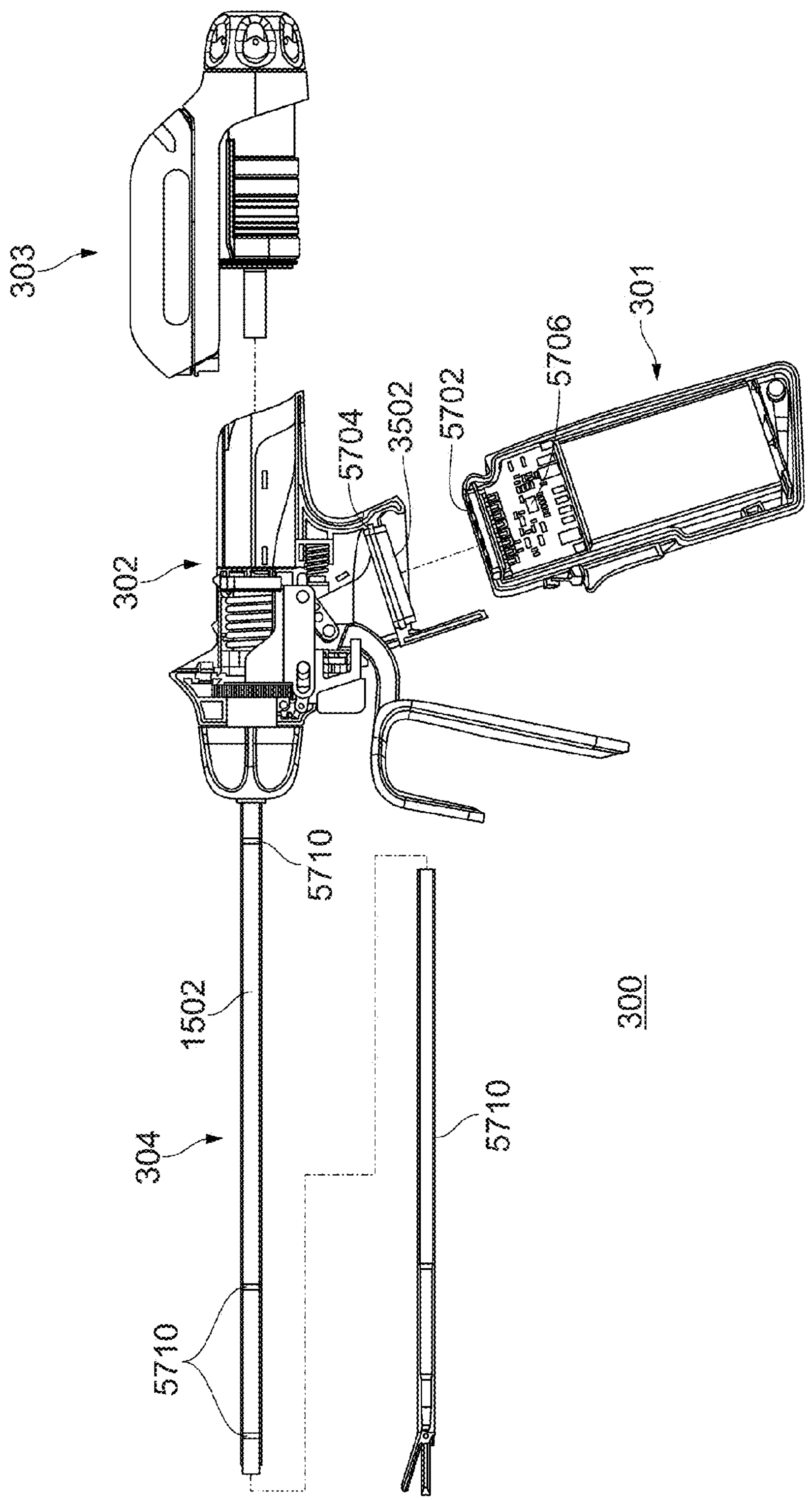


FIG. 57

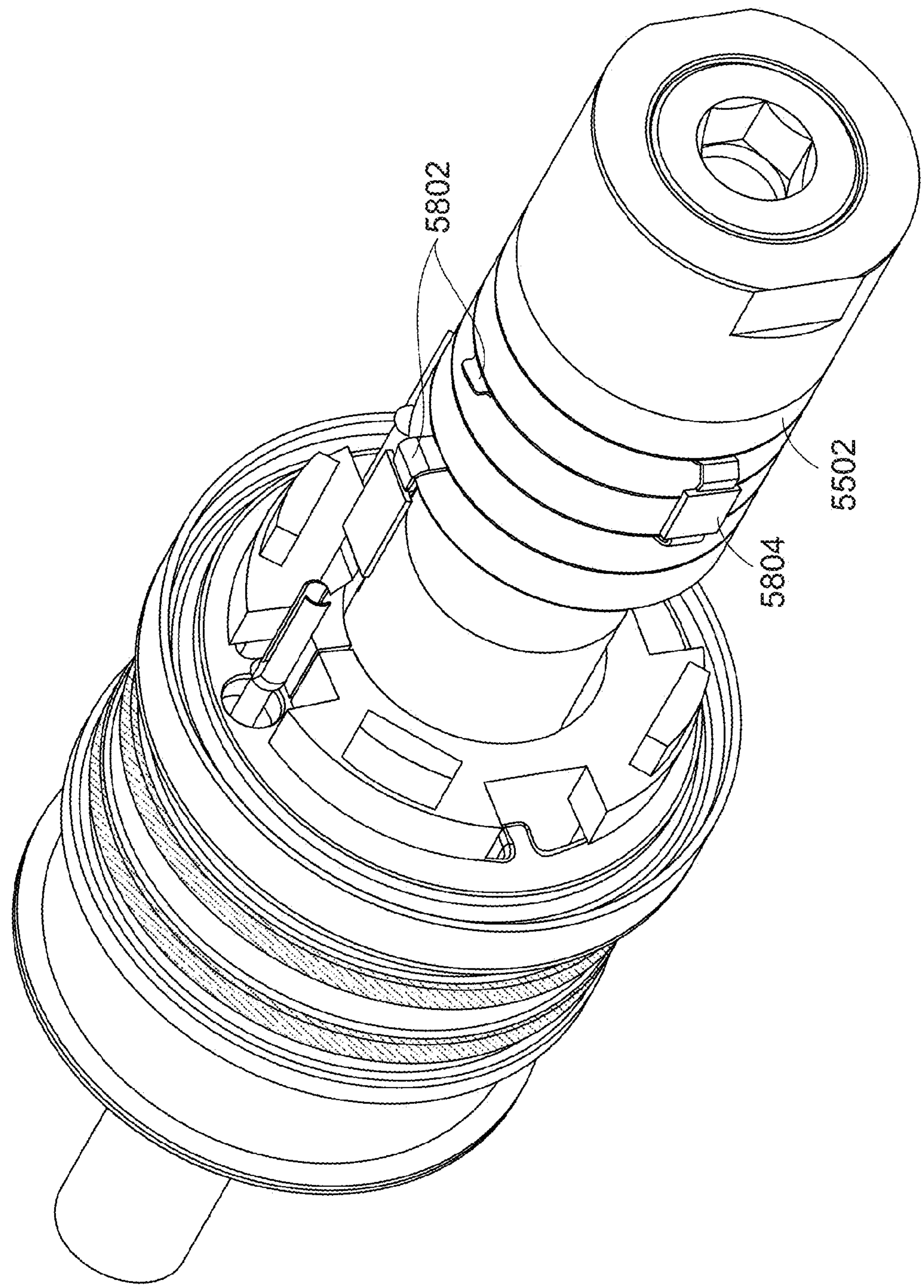


FIG. 58

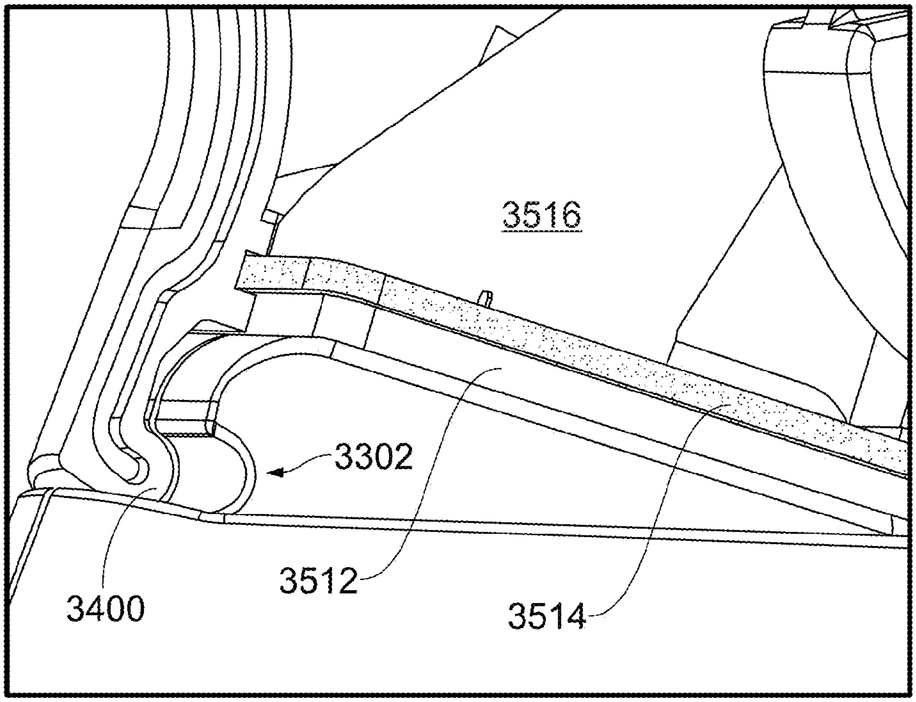


FIG. 59

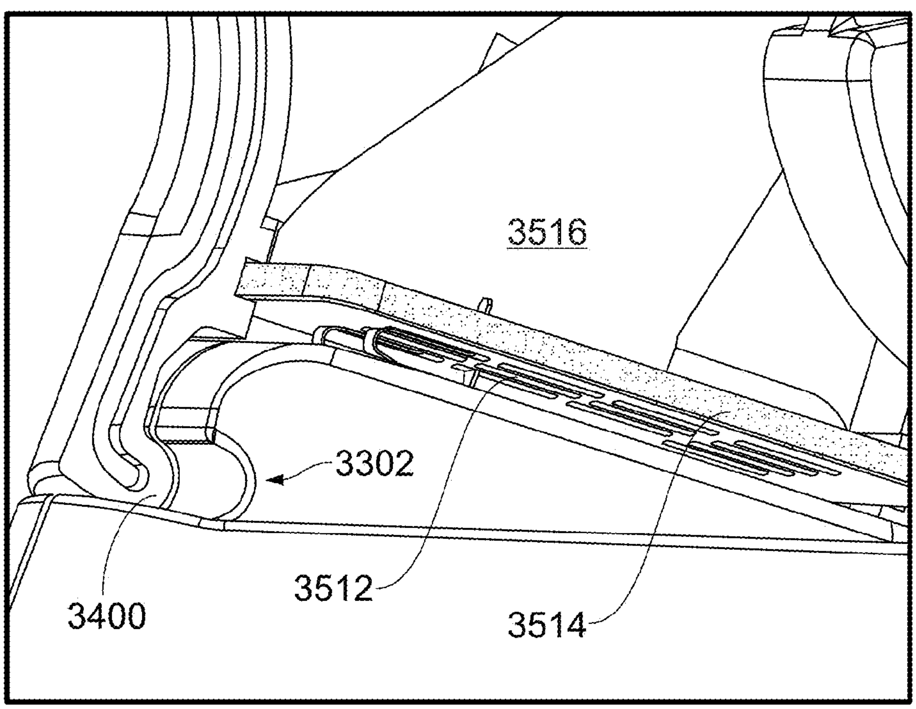


FIG. 60

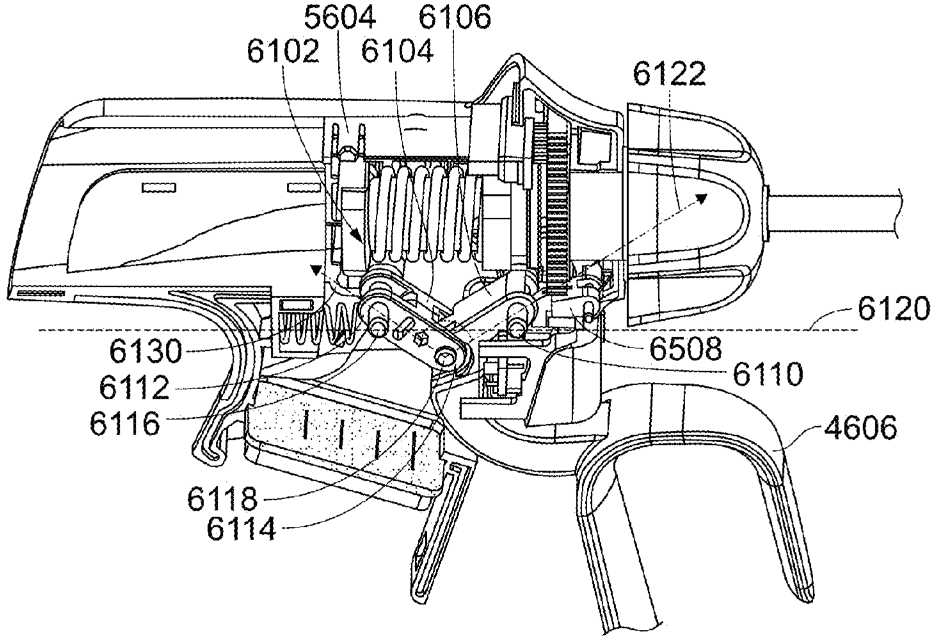

5604
6106
6102
6104
6122
6120
6130
6508
6112
6110
6116
4606
6118
6114

FIG. 61

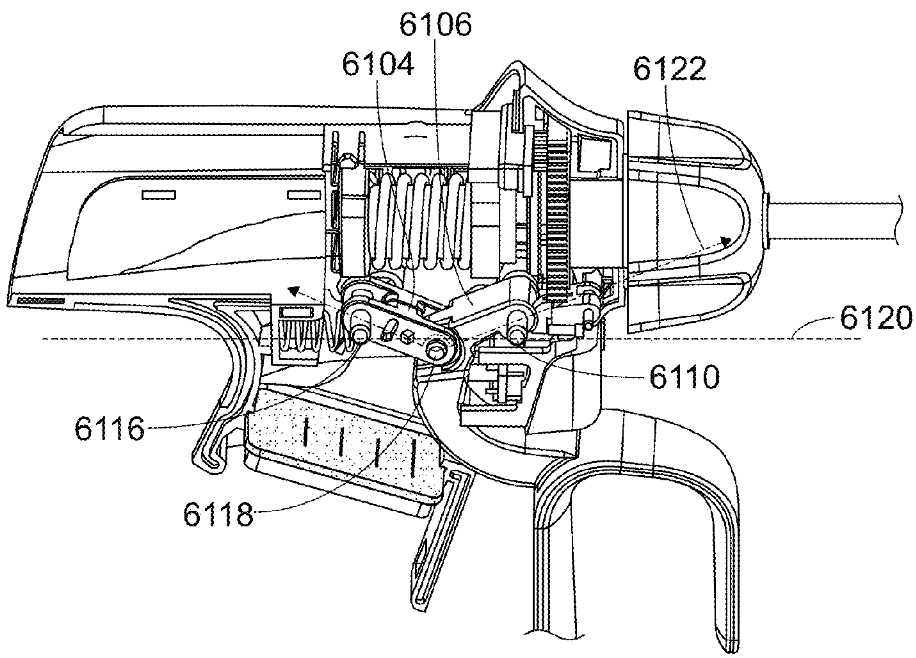

6106
6104
6122
6120
6110
6116
6118

FIG. 62

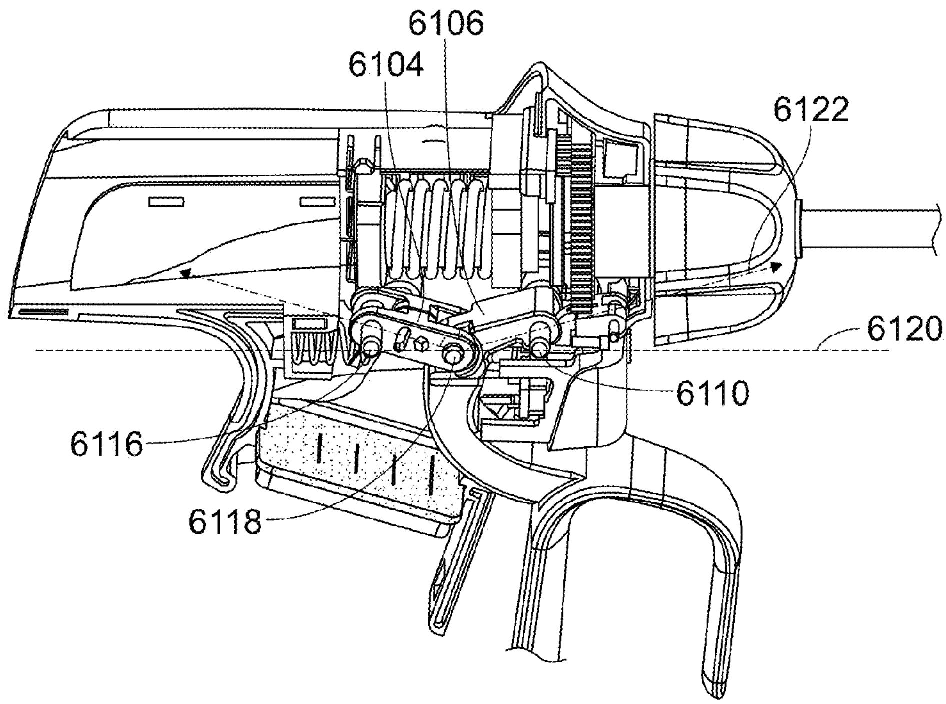

6106
6104
6122
6120
6110
6116
6118

FIG. 63

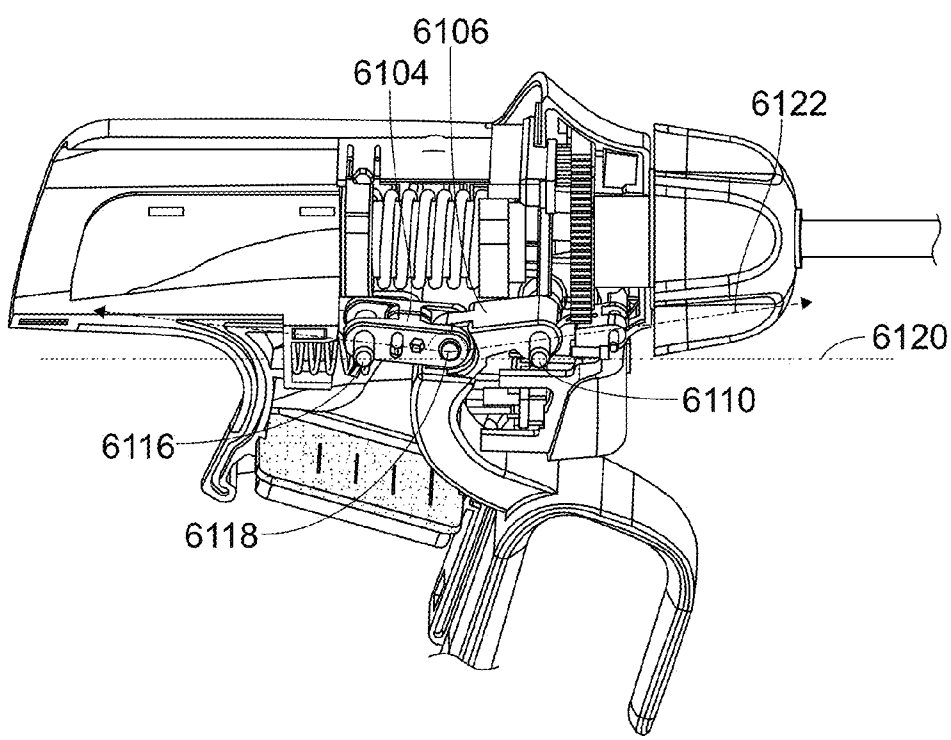

6106
6104
6122
6120
6110
6116
6118

FIG. 64

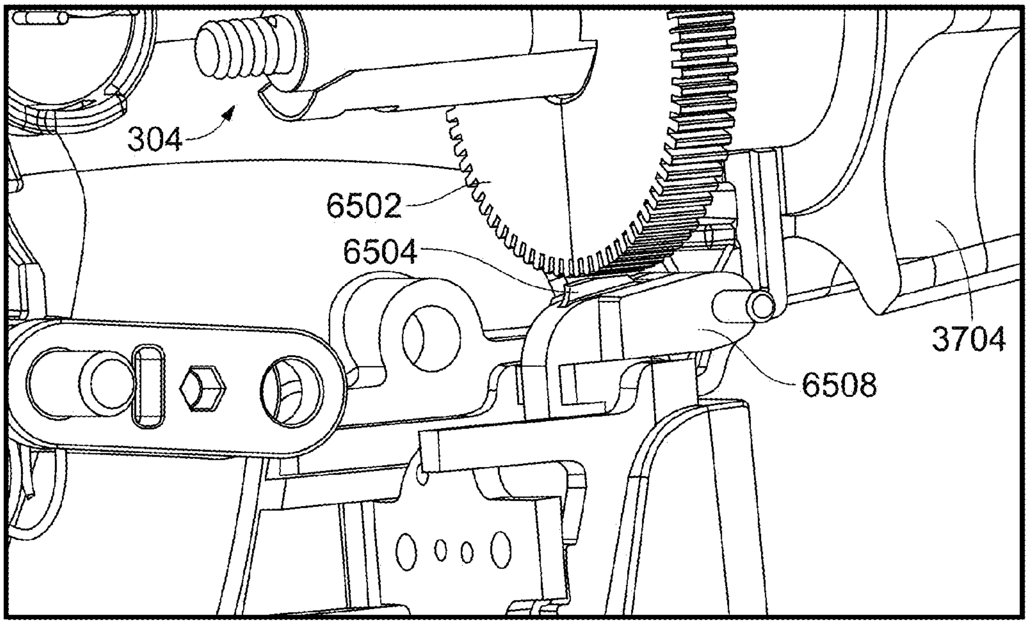

304
6502
6504
3704
6508

FIG. 65

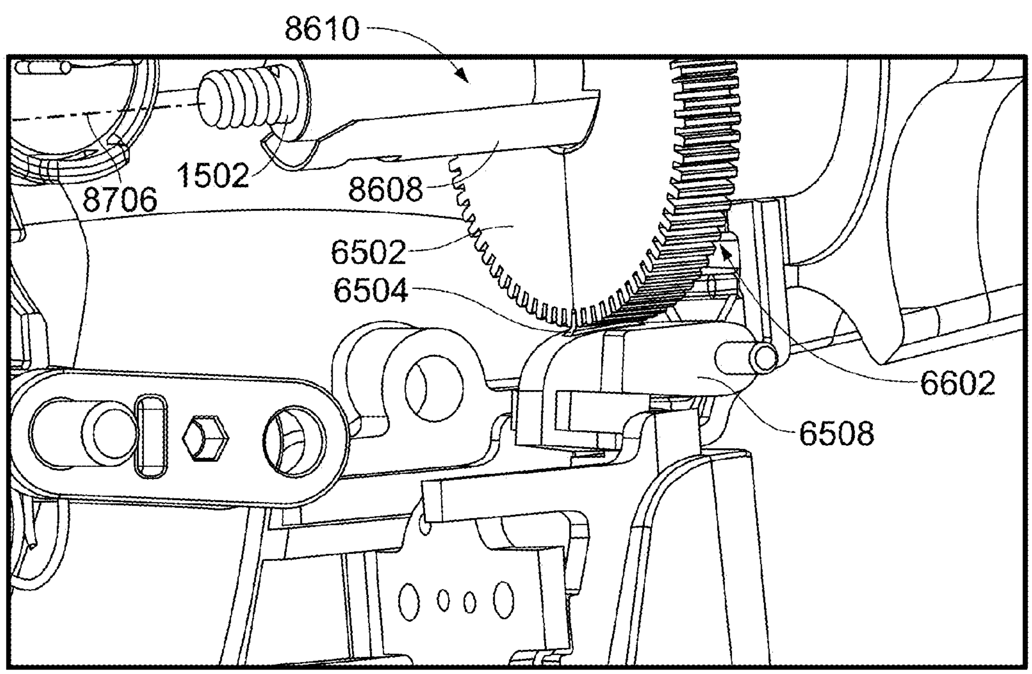

8610
8706
1502
8608
6502
6504
6602
6508

FIG. 66

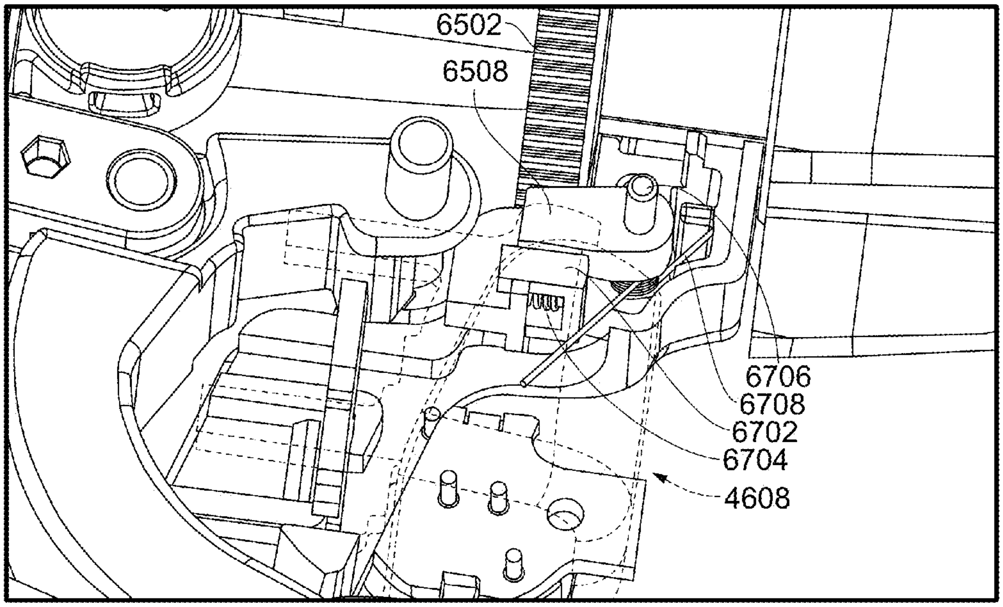


FIG. 67

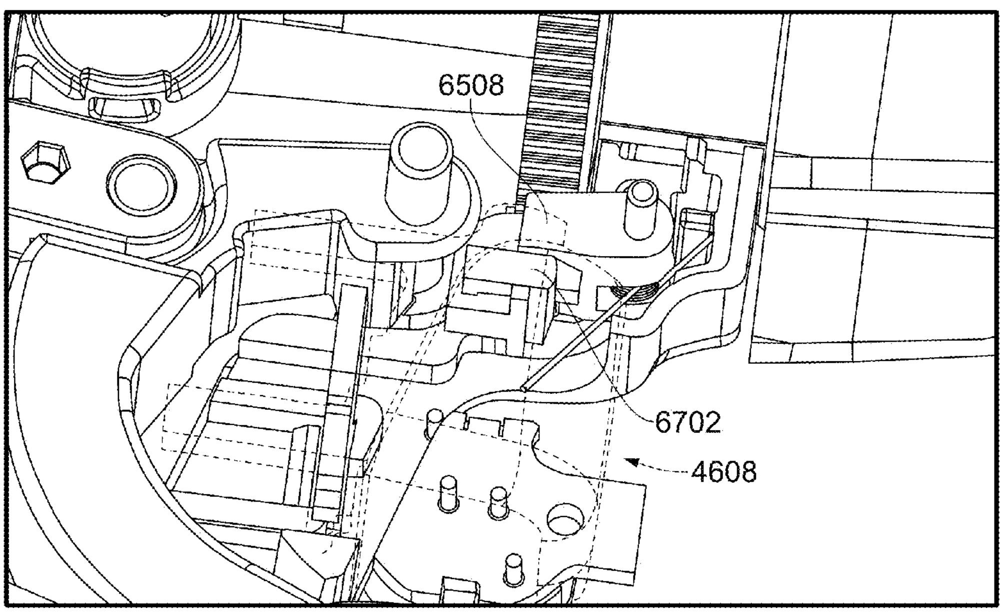


FIG. 68

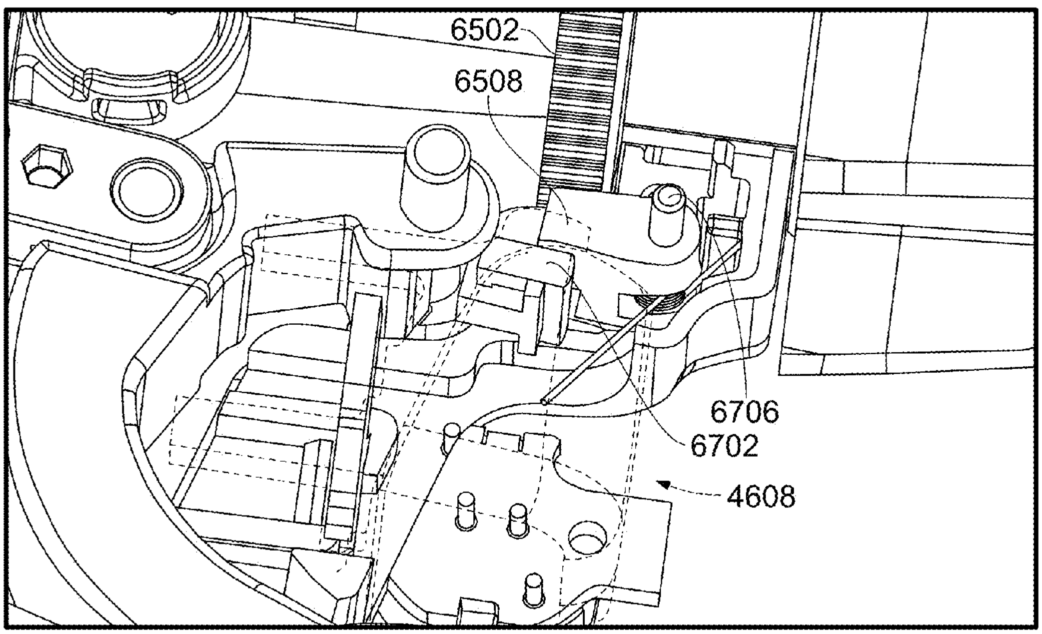


FIG. 69

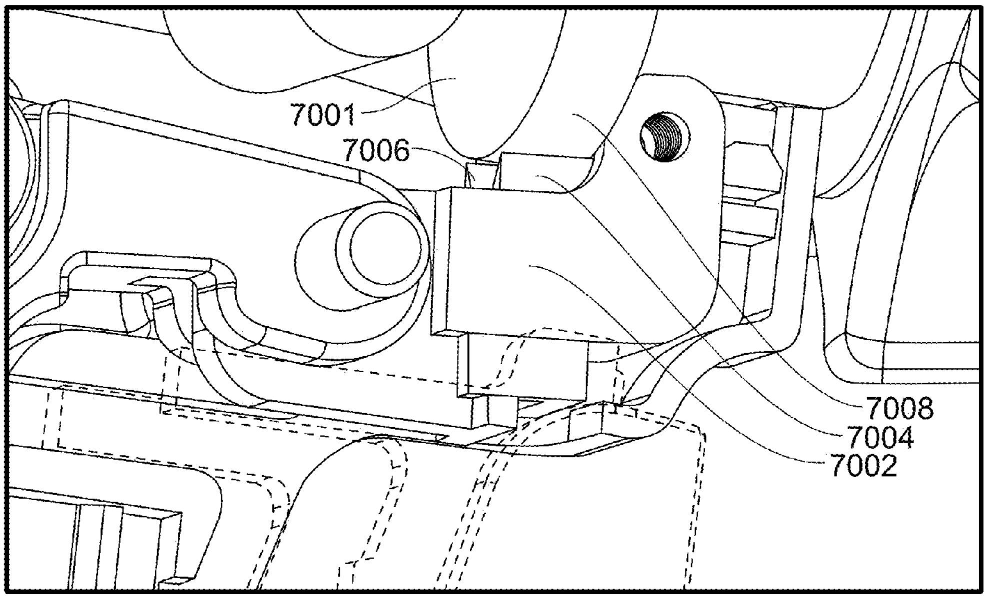


FIG. 70

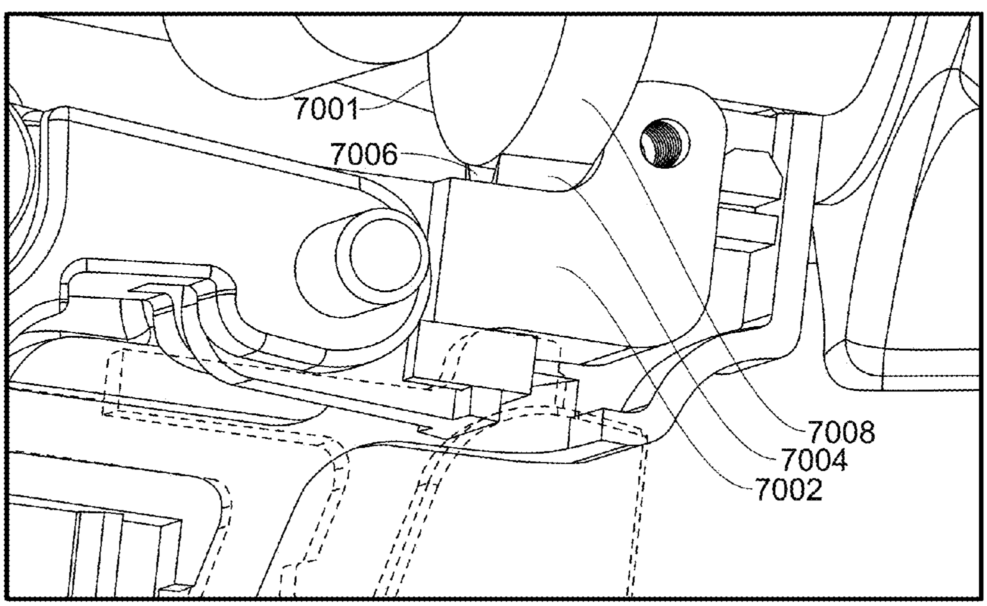


FIG. 71

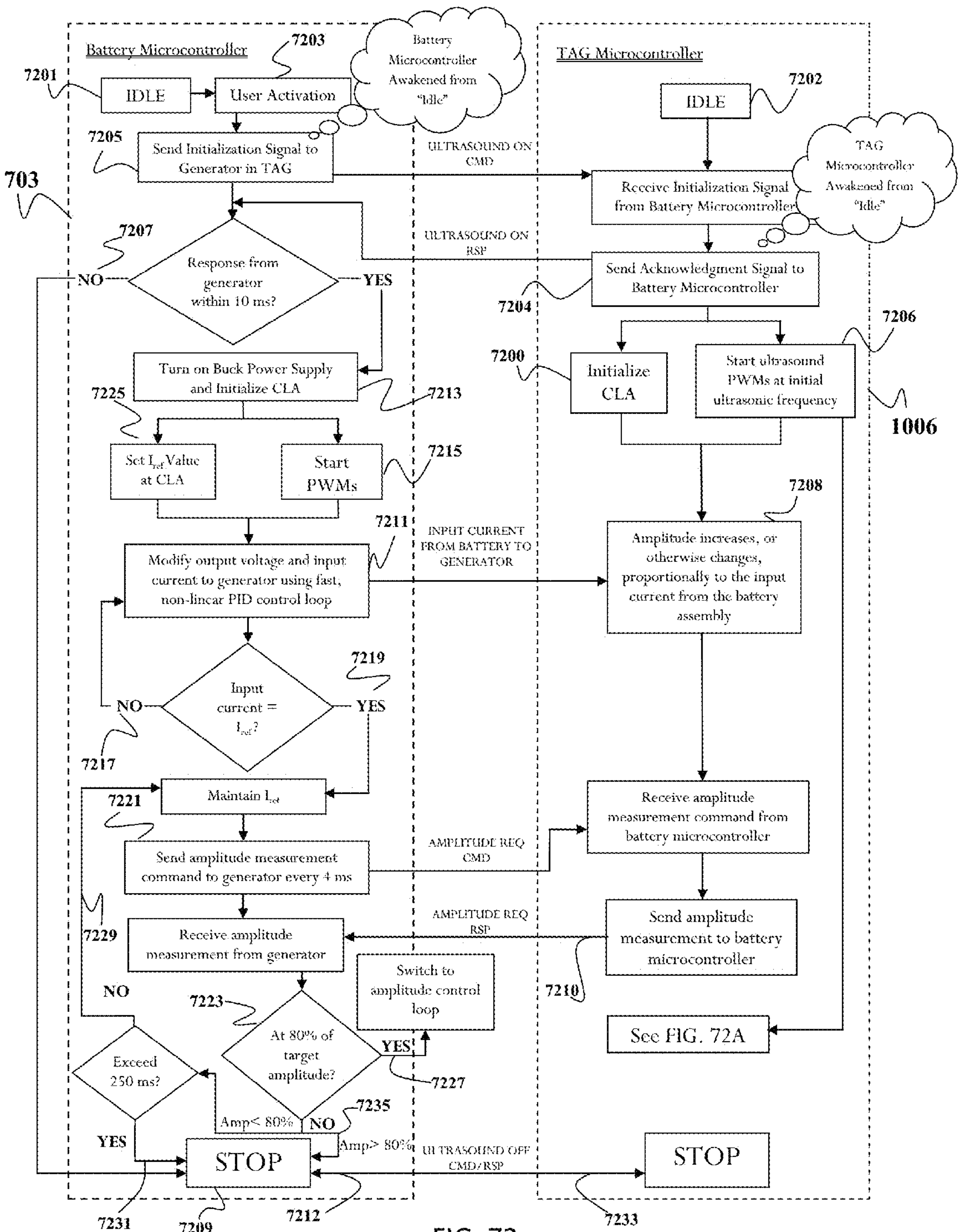

Battery Microcontroller
TAG Microcontroller
Battery Microcontroller Awakened from "Idle"
IDLE
User Activation
Send Initialization Signal to Generator in TAG
ULTRASOUND ON CMD
Receive Initialization Signal from Battery Microcontroller
TAG Microcontroller Awakened from "Idle"
ULTRASOUND ON RSP
Response from generator within 10 ms?
NO
YES
Send Acknowledgment Signal to Battery Microcontroller
Turn on Buck Power Supply and Initialize CLA
Initialize CLA
Start ultrasound PWMs at initial ultrasonic frequency
Set I_{ref} Value at CLA
Start PWMs
INPUT CURRENT FROM BATTERY TO GENERATOR
Modify output voltage and input current to generator using fast, non-linear PID control loop
Amplitude increases, or otherwise changes, proportionally to the input current from the battery assembly
Input current = I_{ref}?
Maintain I_{ref}
Receive amplitude measurement command from battery microcontroller
Send amplitude measurement command to generator every 4 ms
AMPLITUDE REQ CMD
AMPLITUDE REQ RSP
Send amplitude measurement to battery microcontroller
Receive amplitude measurement from generator
Switch to amplitude control loop
At 80% of target amplitude?
Exceed 250 ms?
See FIG. 72A
Amp< 80%
Amp> 80%
STOP
ULTRASOUND OFF CMD/RSP
703
1006
7200
7201
7202
7203
7204
7205
7206
7207
7208
7209
7210
7211
7212
7213
7215
7217
7219
7221
7223
7225
7227
7229
7231
7233
7235

FIG. 72

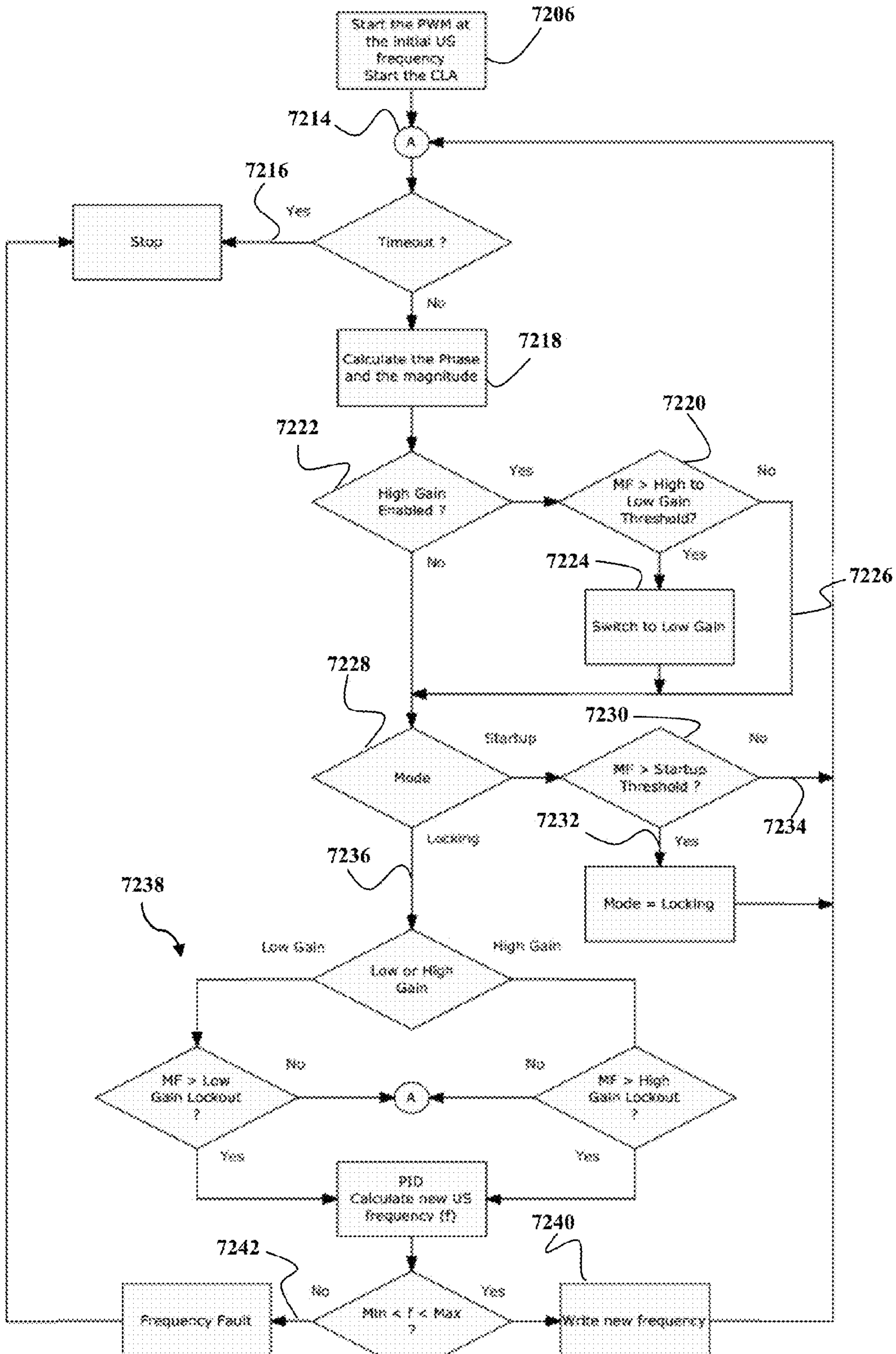

Start the PWM at the initial US frequency Start the CLA
7206
7214
A
7216
Yes
Stop
Timeout ?
No
Calculate the Phase and the magnitude
7218
7222
7220
High Gain Enabled ?
Yes
MF > High to Low Gain Threshold?
No
No
Yes
7224
Switch to Low Gain
7226
7228
7230
Mode
Startup
MF > Startup Threshold ?
No
7234
7232
Yes
Locking
Mode = Locking
7236
7238
Low Gain
Low or High Gain
High Gain
MF > Low Gain Lockout ?
No
A
No
MF > High Gain Lockout ?
Yes
Yes
PID Calculate new US frequency (f)
7240
7242
No
Yes
Frequency Fault
Min < f < Max ?
Write new frequency

FIG. 72A

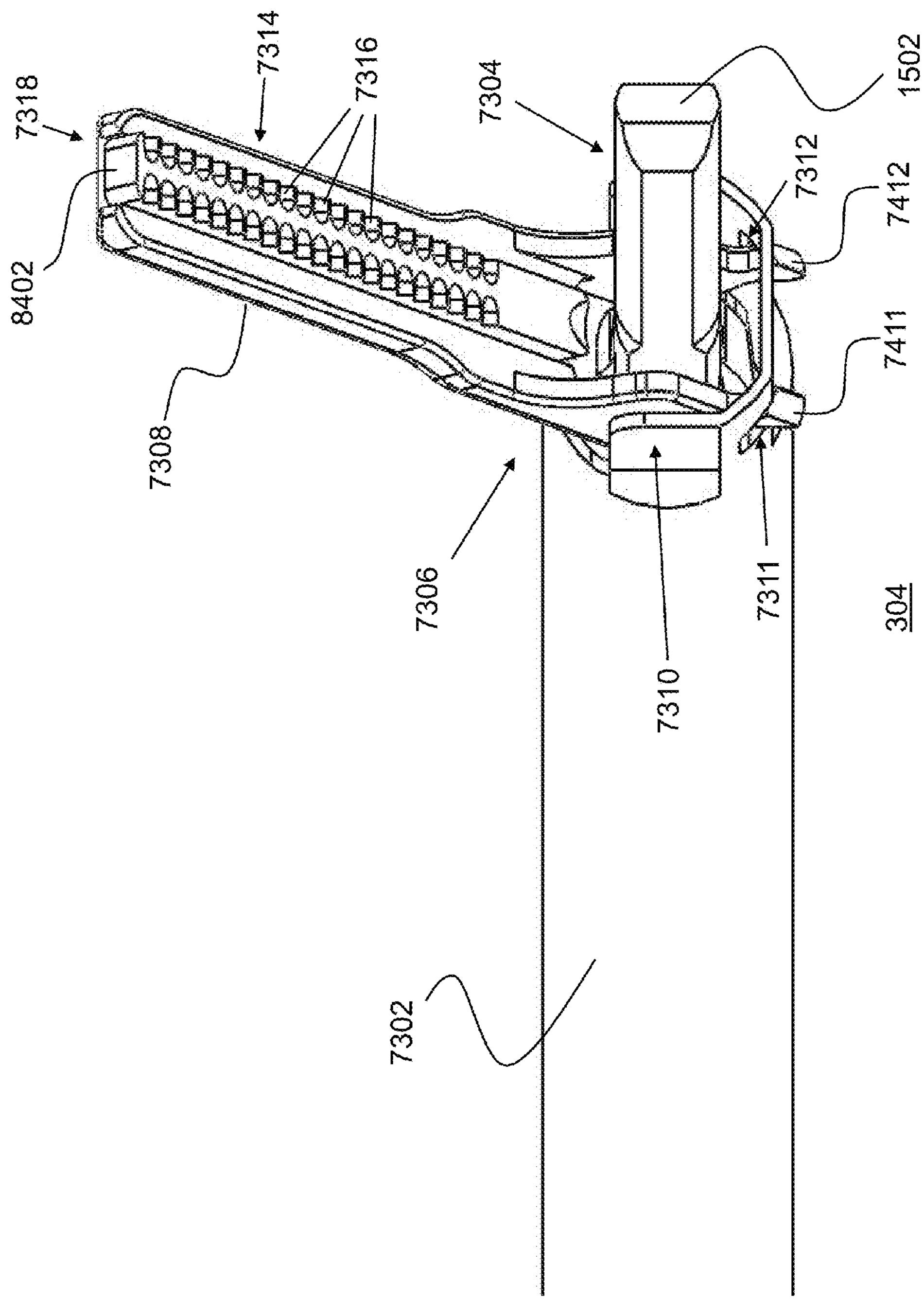

7318
7314
7316
7304
1502
7312
7412
8402
7411
7308
7306
7310
7311
304
7302

FIG. 73

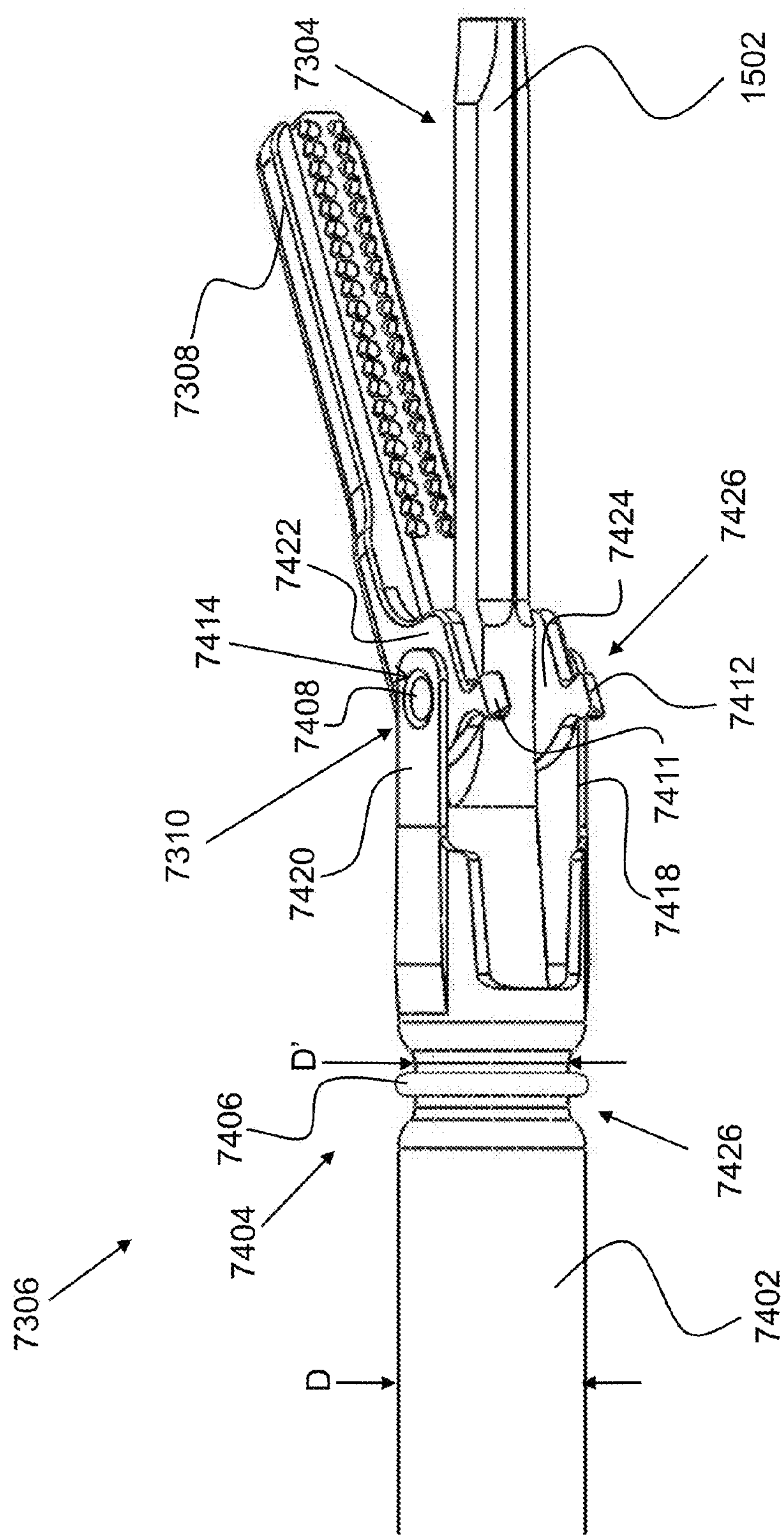

7304
1502
7308
7422
7424
7426
7414
7408
7412
7411
7310
7420
7418
D'
7406
7426
7404
7306
7402
D

FIG. 74

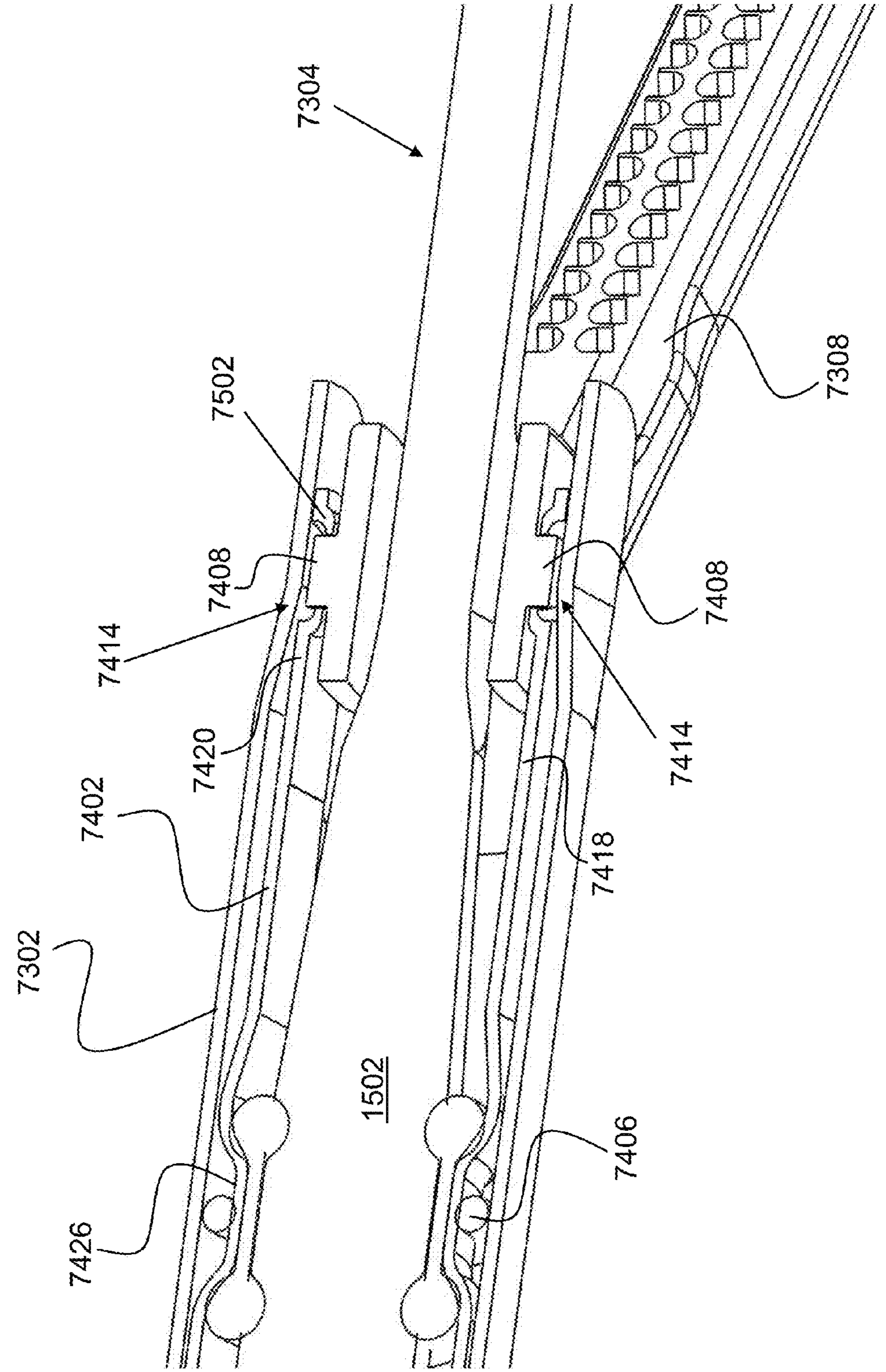

7304
7502
7408
7414
7420
7402
7302
1502
7426
7308
7408
7414
7418
7406

FIG. 75

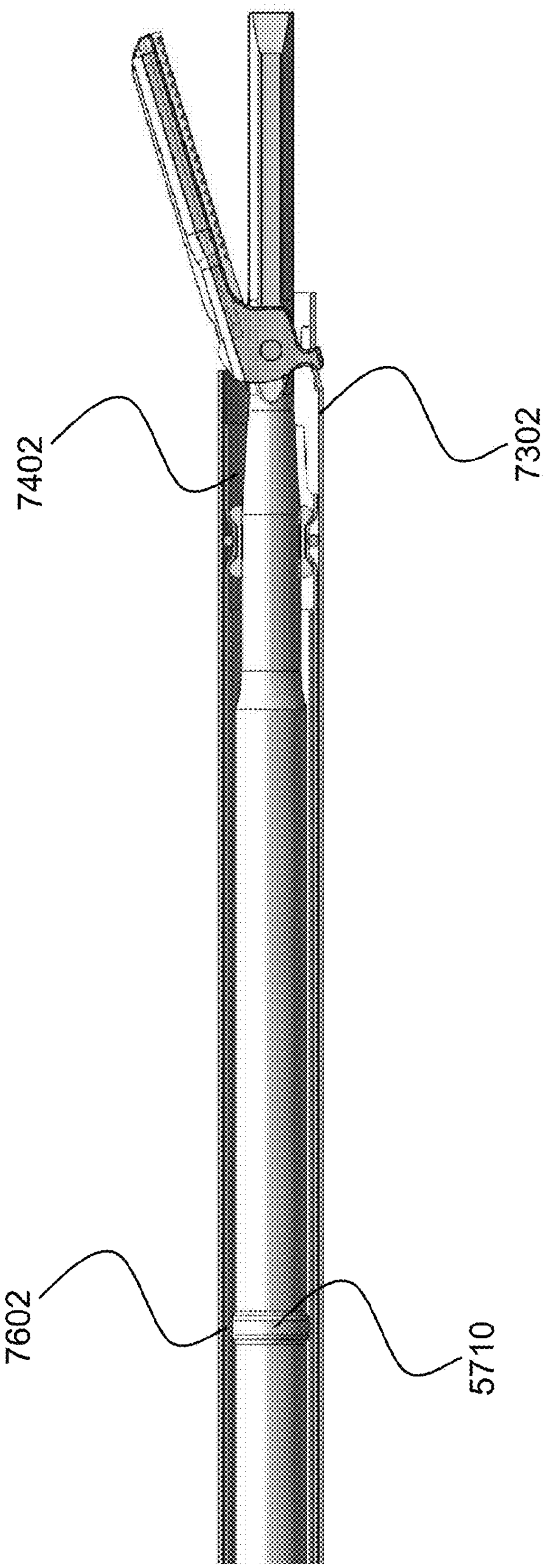


FIG. 76

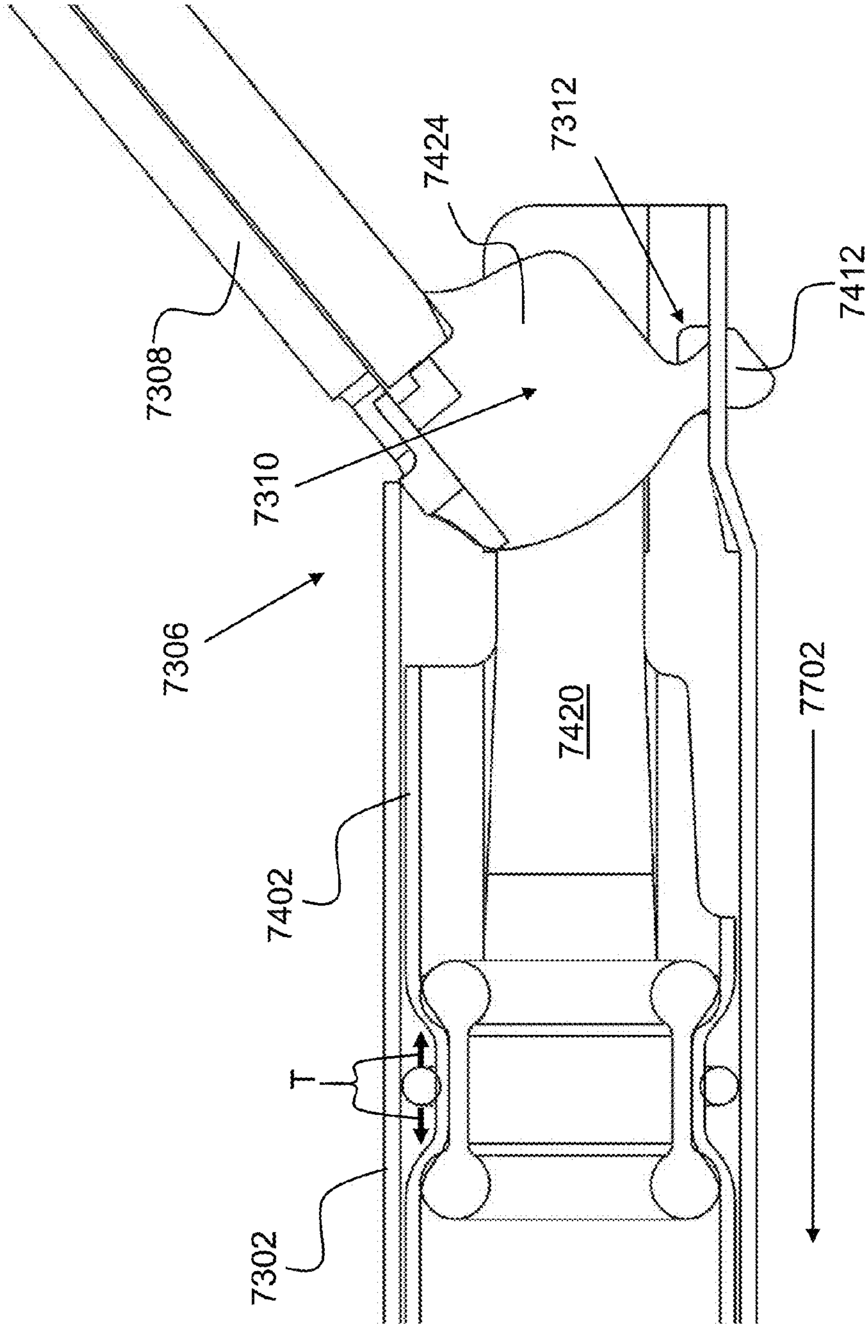


FIG. 77

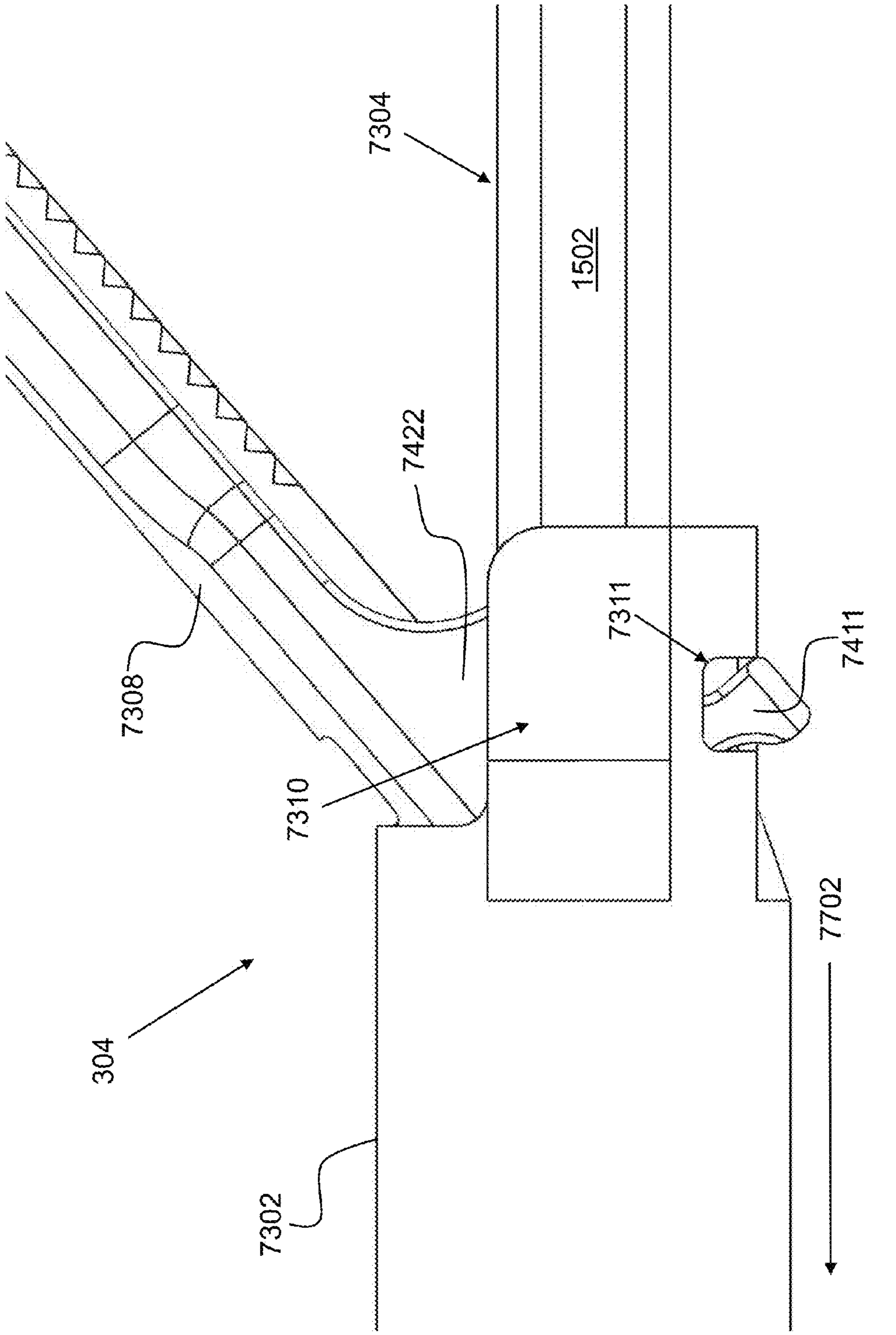


FIG. 78

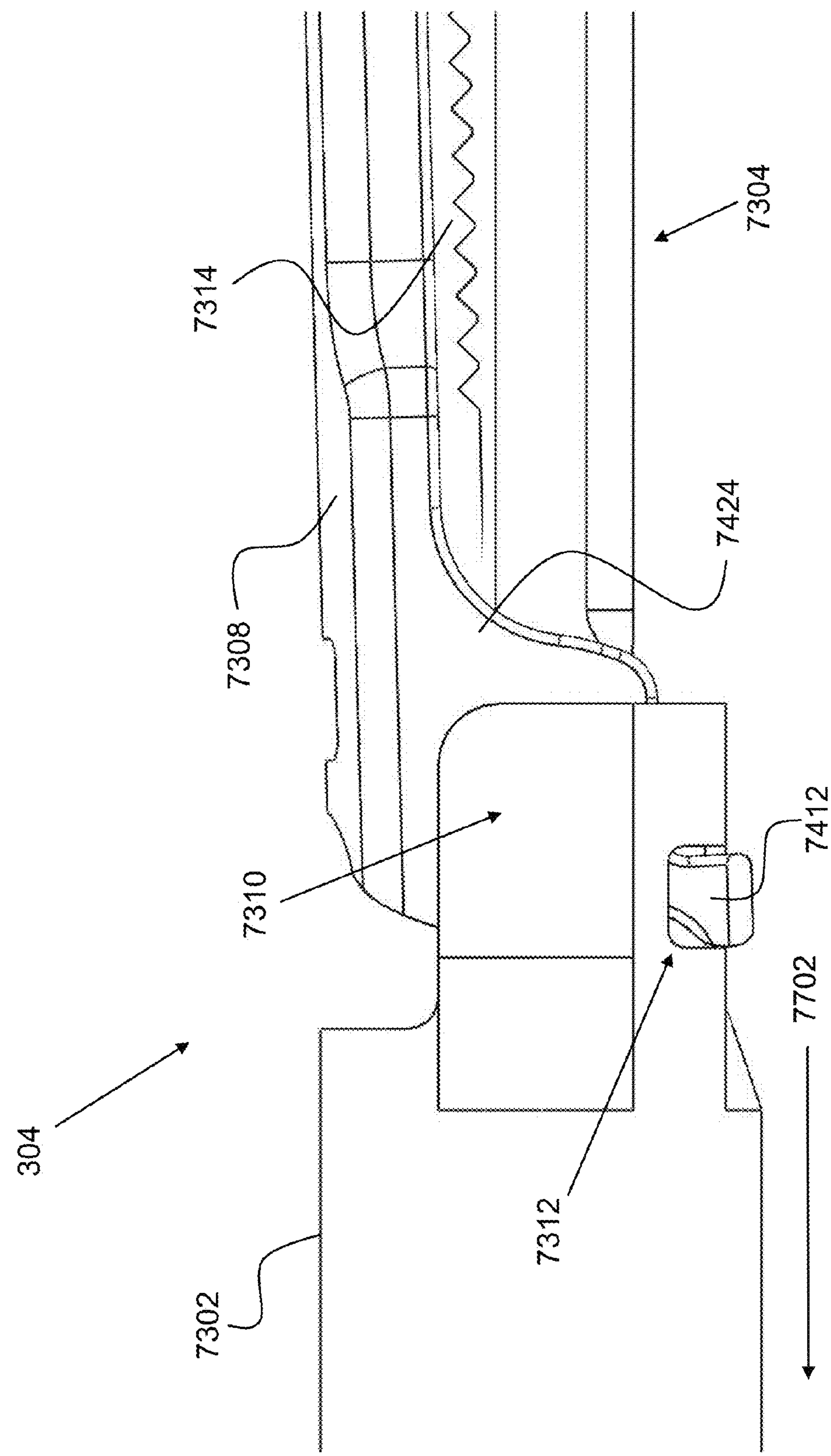


FIG. 79

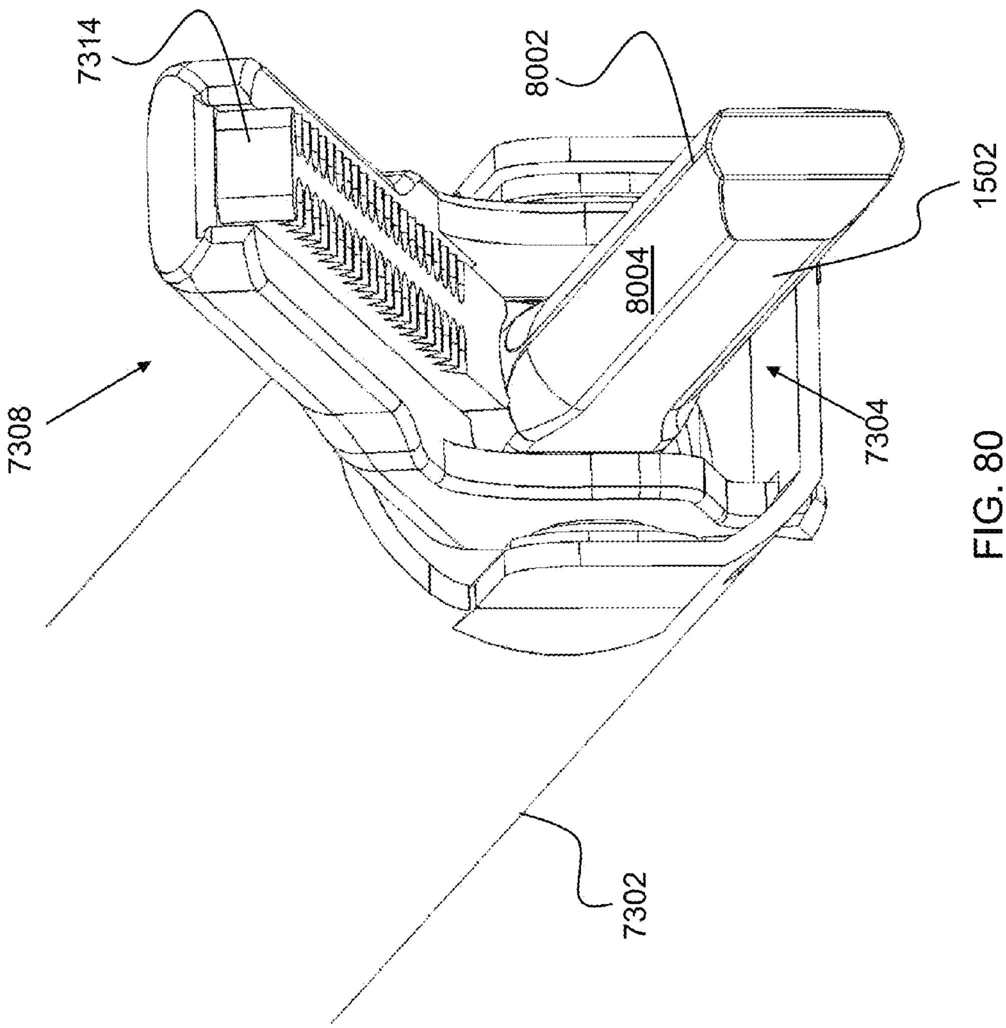


FIG. 80

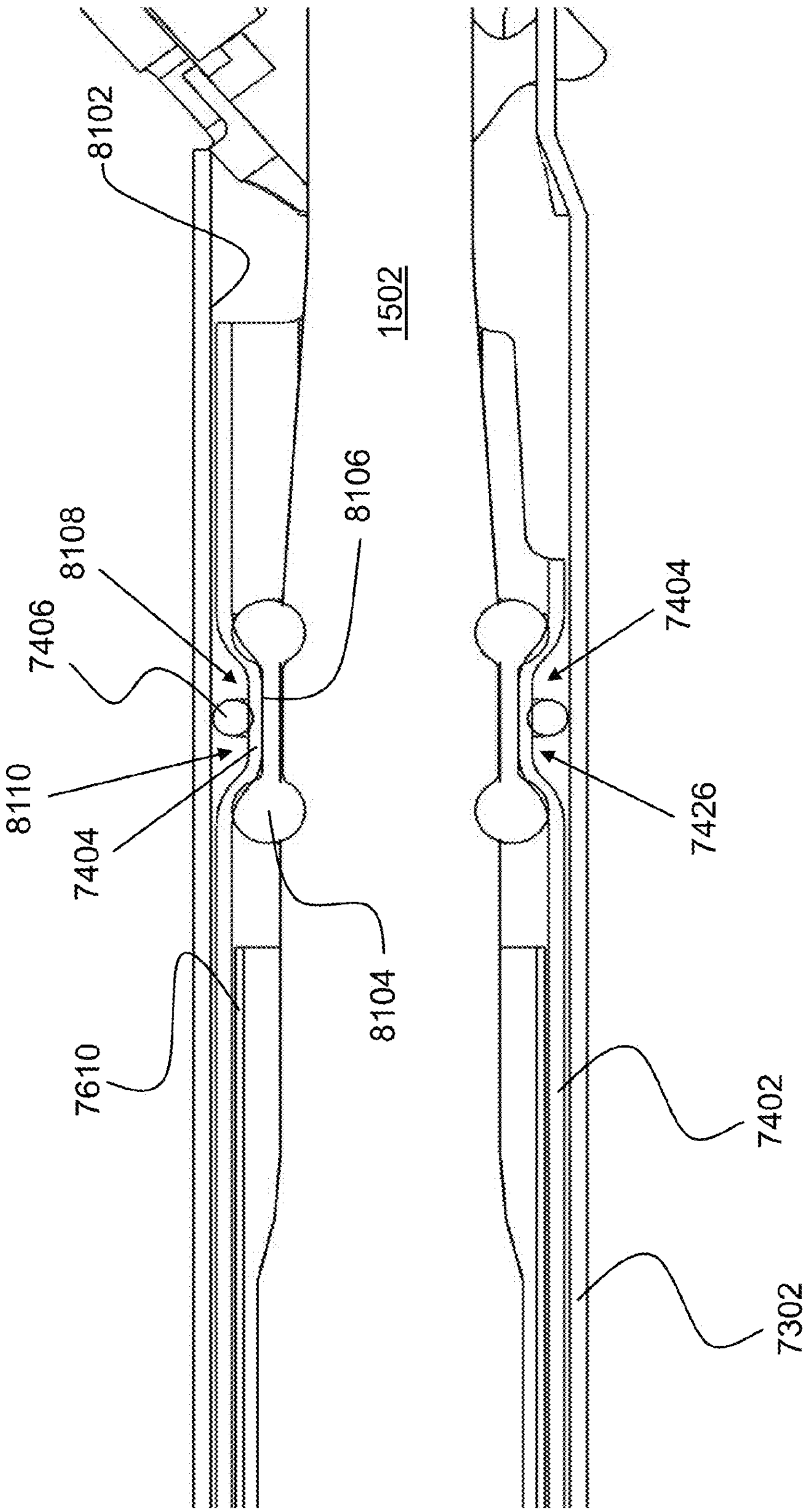
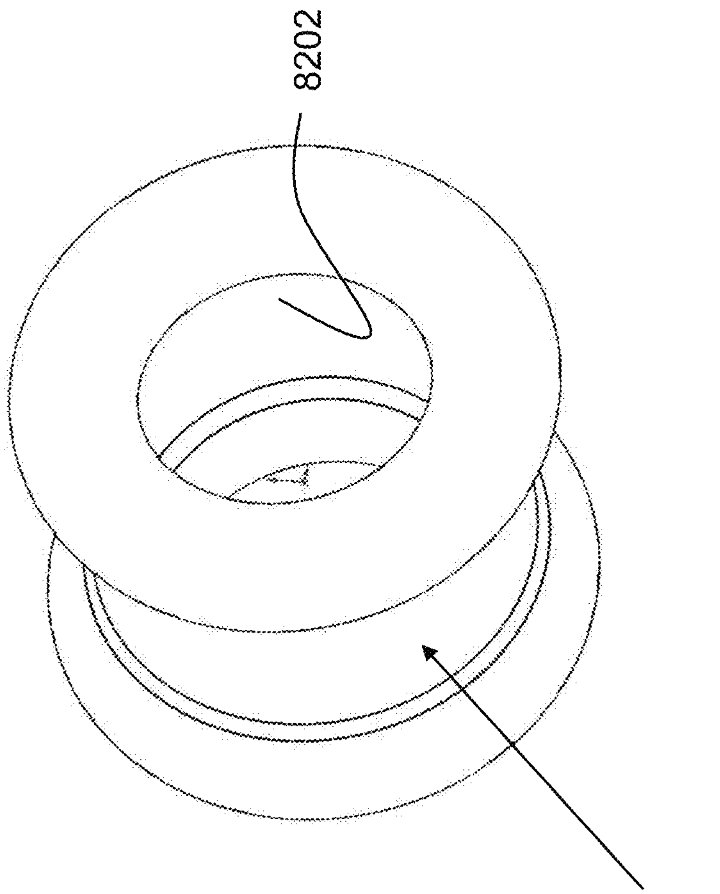

8102
1502
8106
8108
7406
8110
7404
8104
7610
7404
7426
7402
7302

FIG. 81



8104

FIG. 82

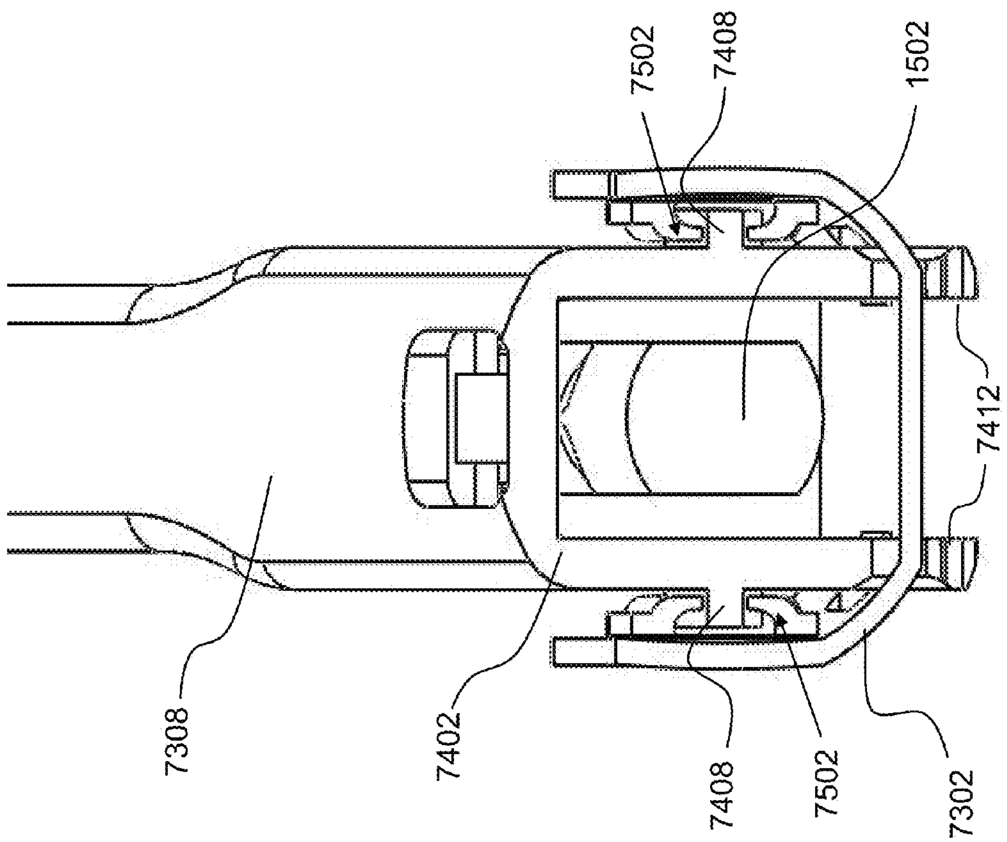


FIG. 83

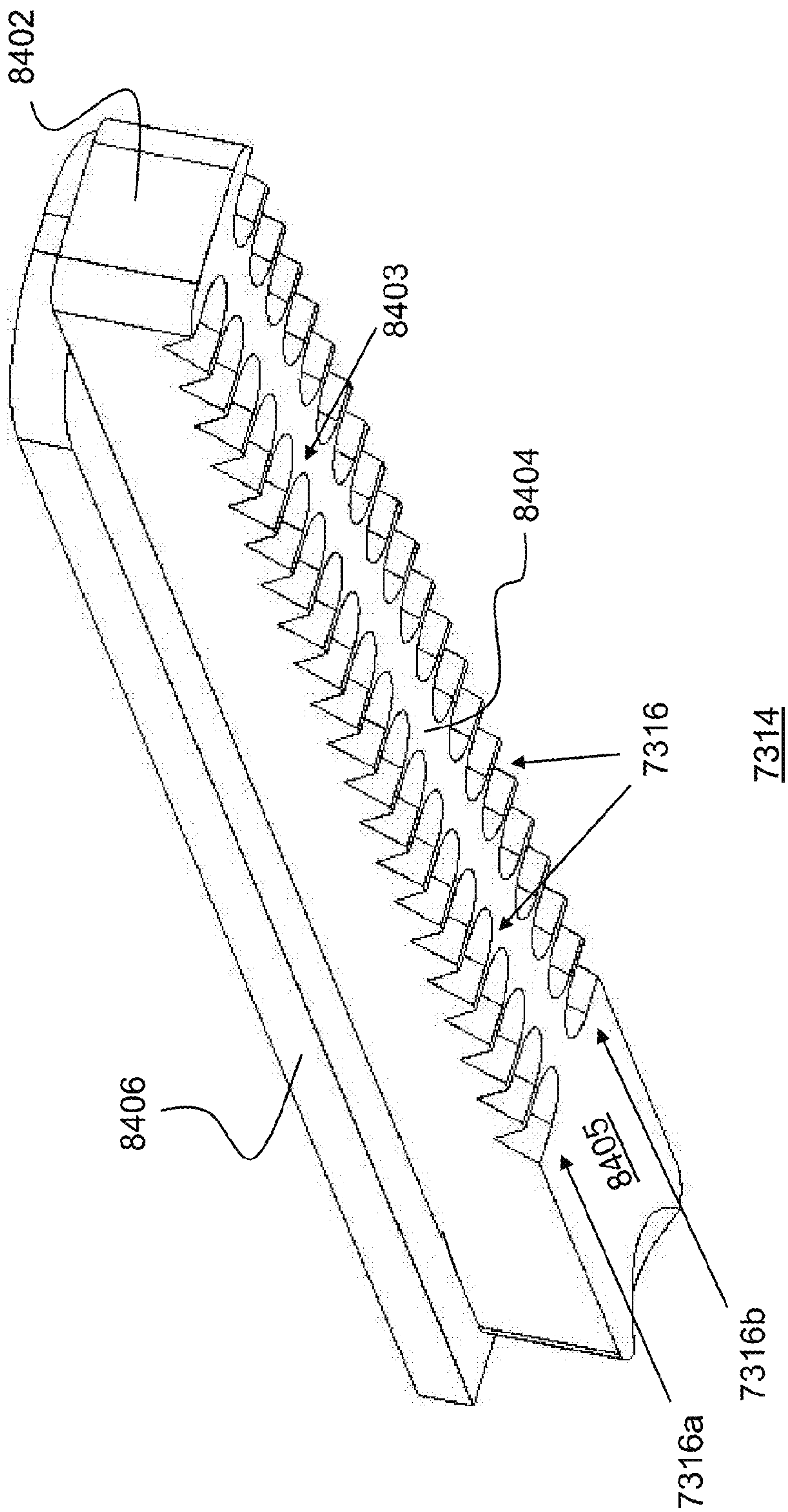


FIG. 84

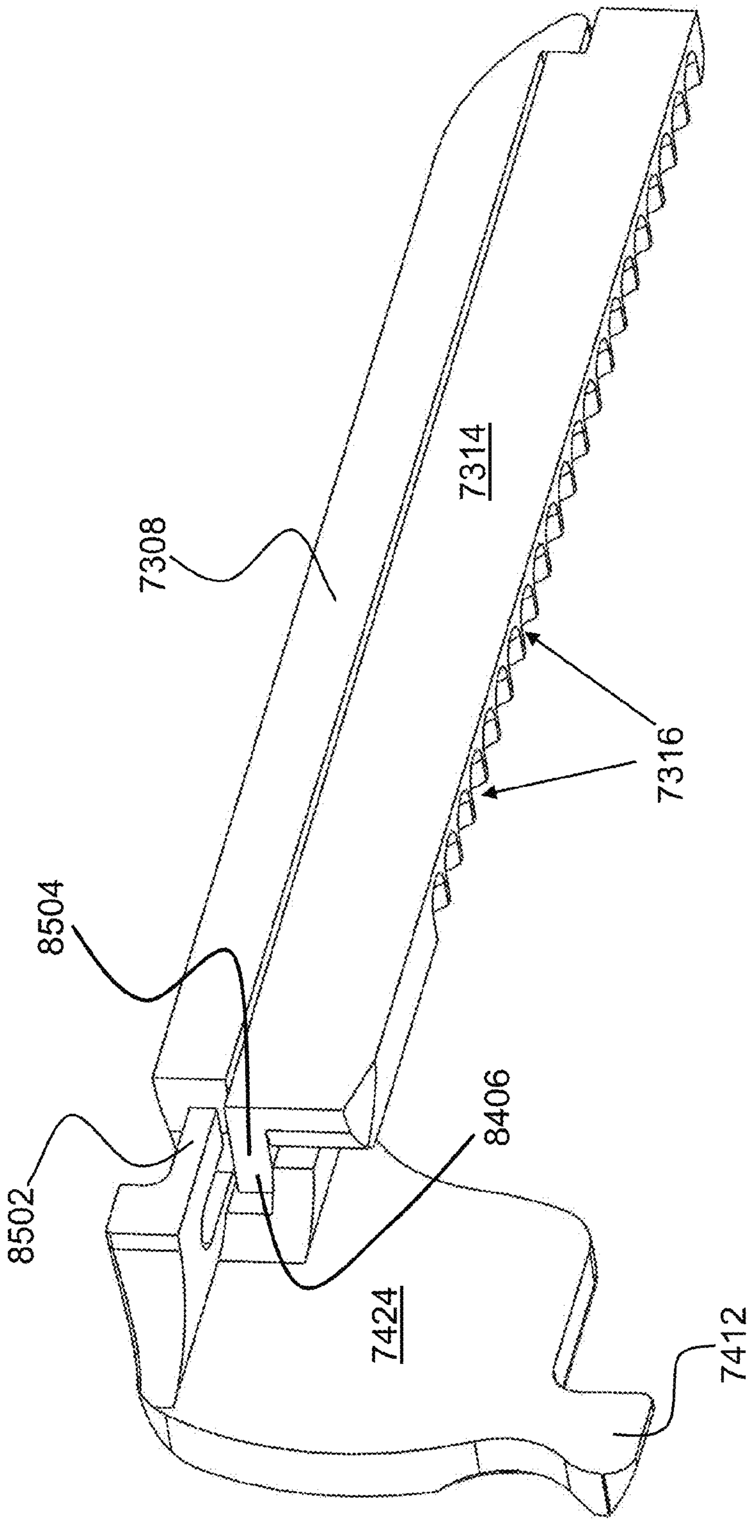


FIG. 85

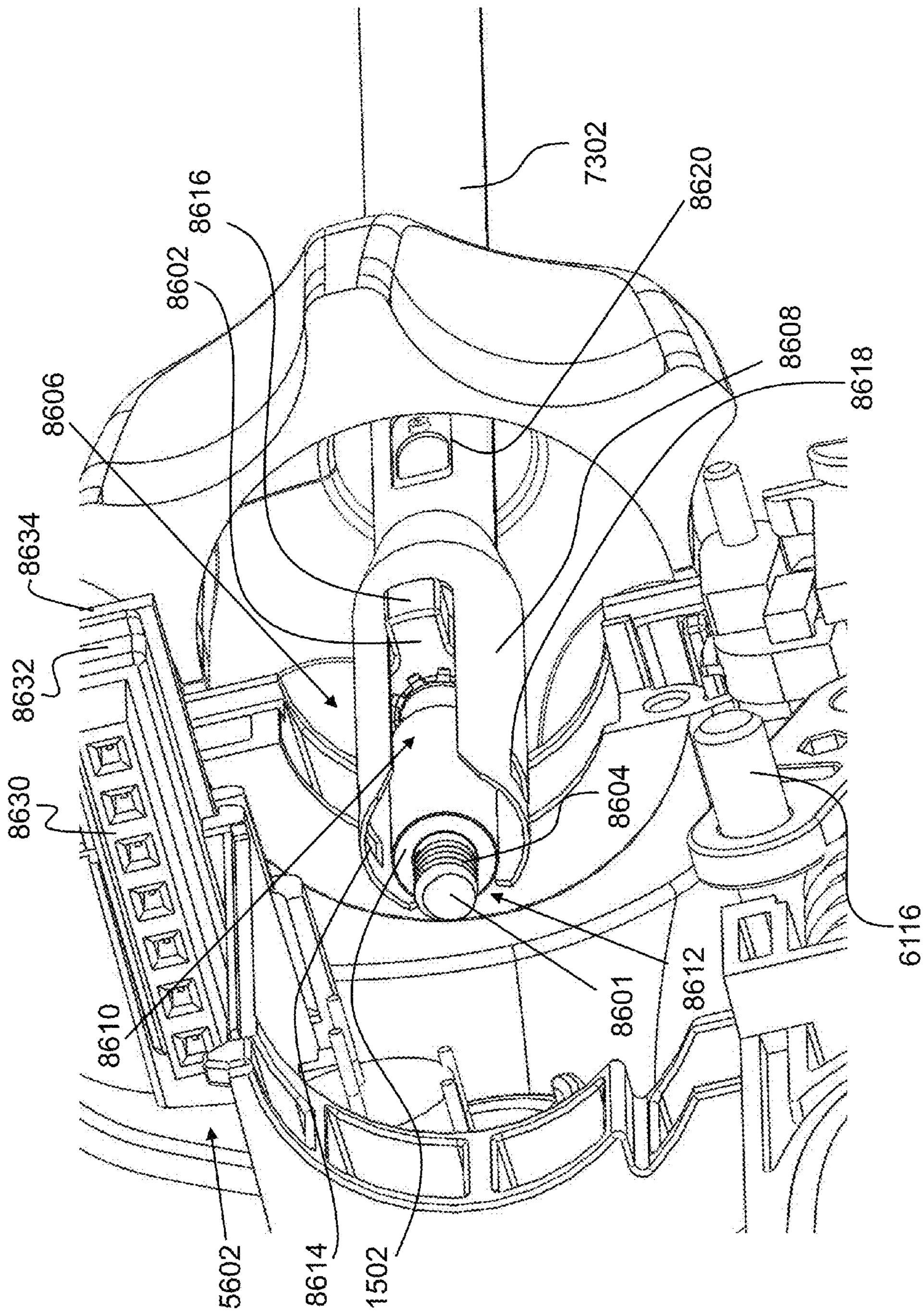

7302
8620
8616
8602
8608
8618
8606
8634
8632
8630
8604
6116
8601
8612
8610
5602
8614
1502

FIG. 86

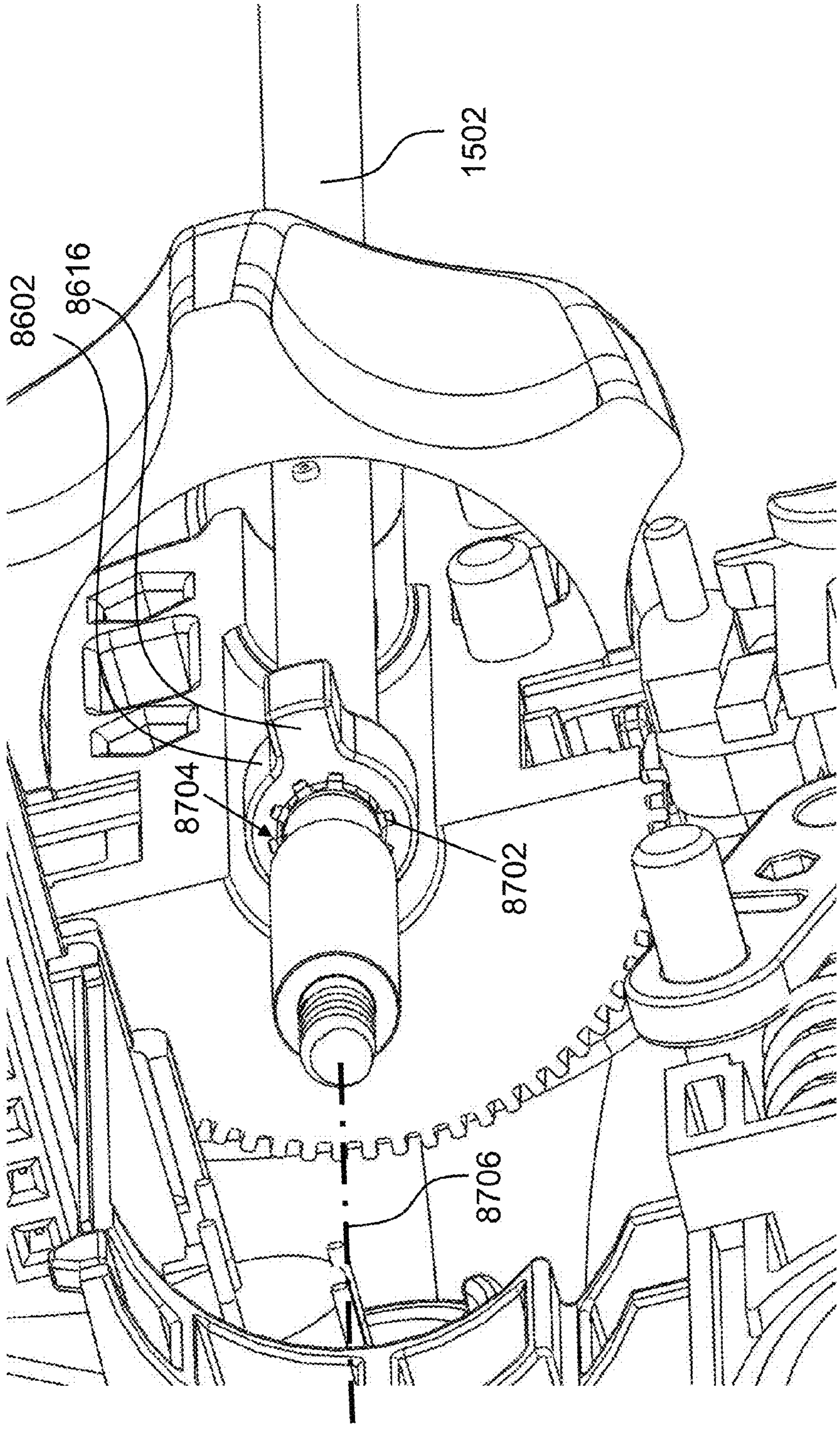


FIG. 87

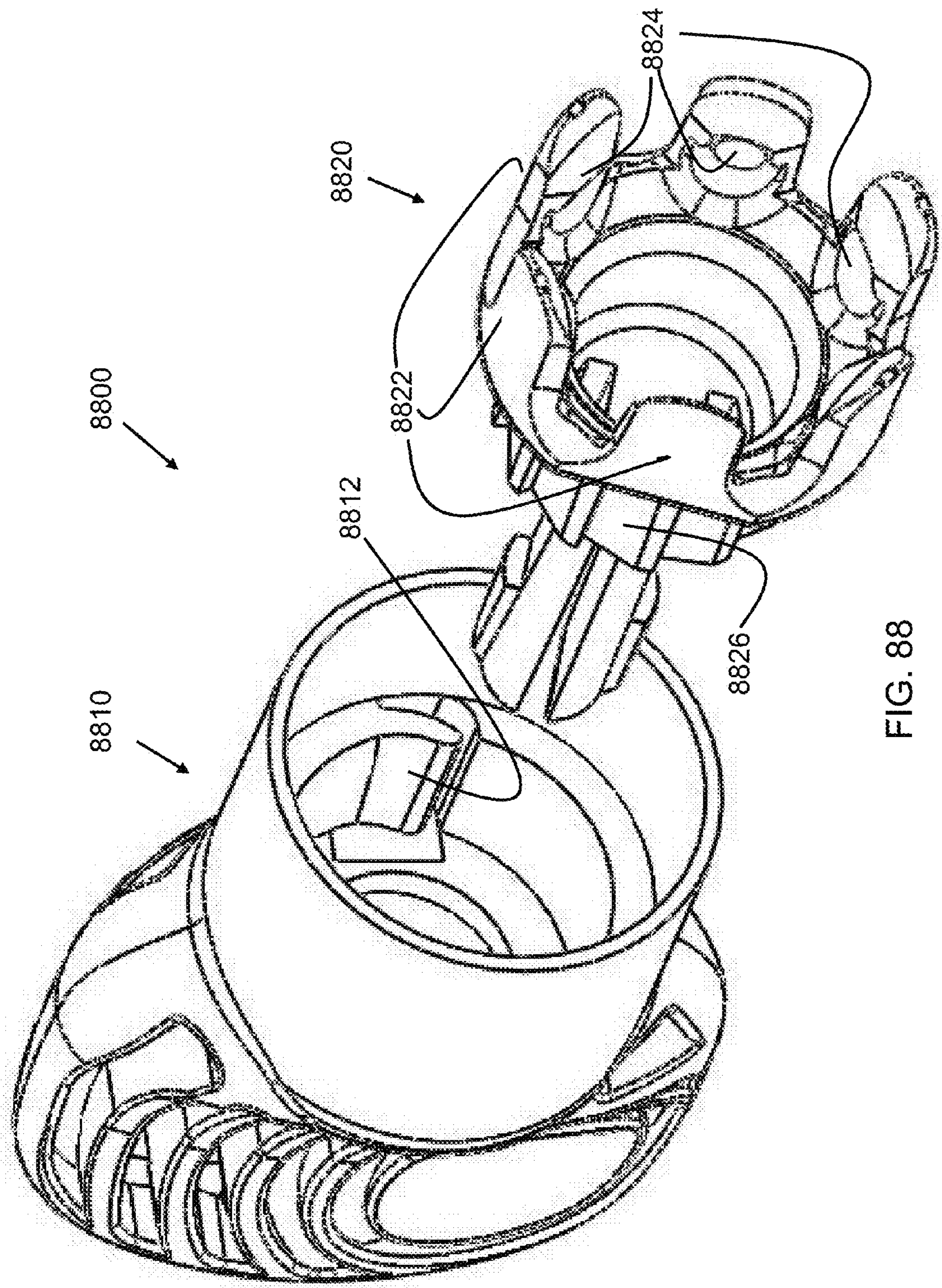


FIG. 88

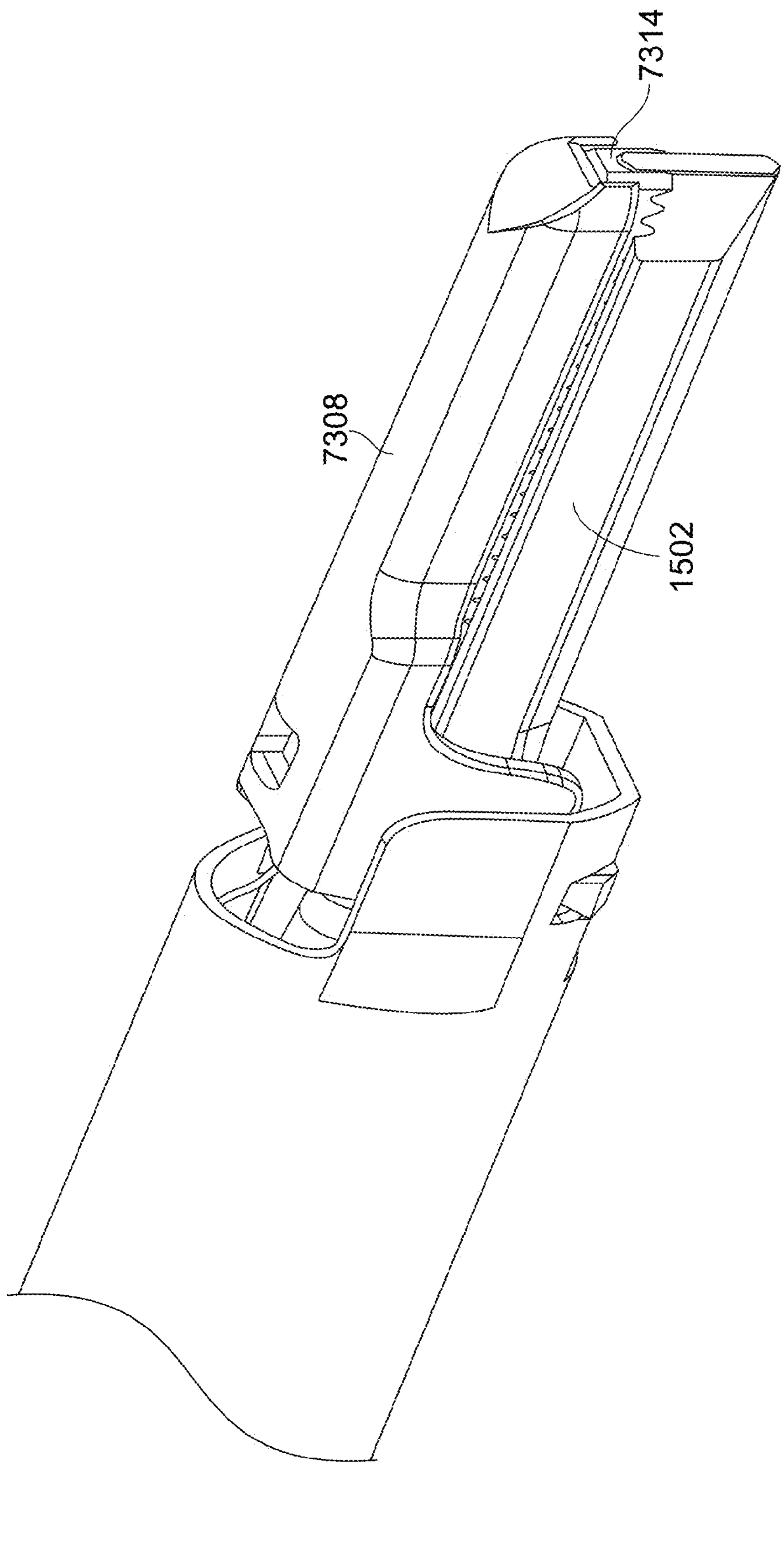


FIG. 89

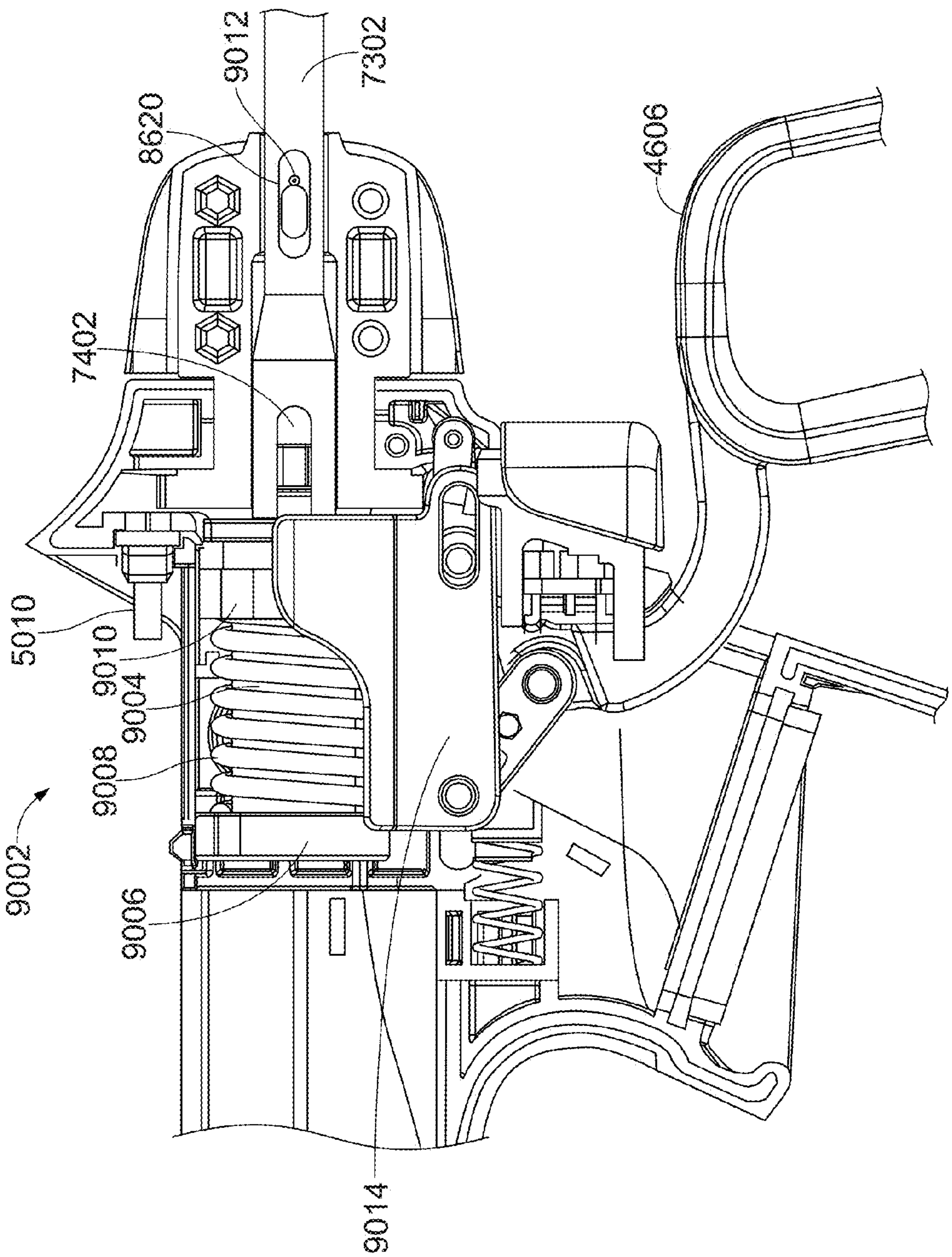


FIG. 90

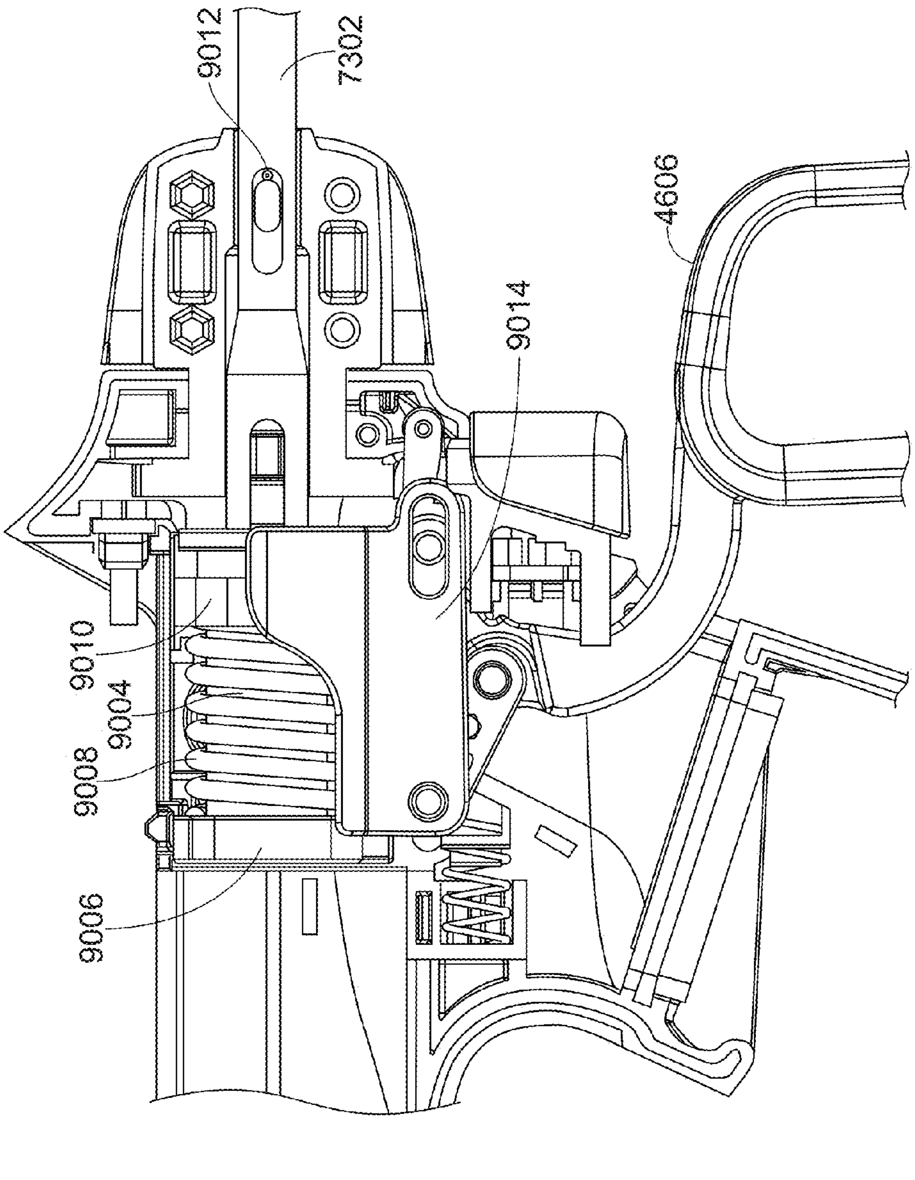


FIG. 91

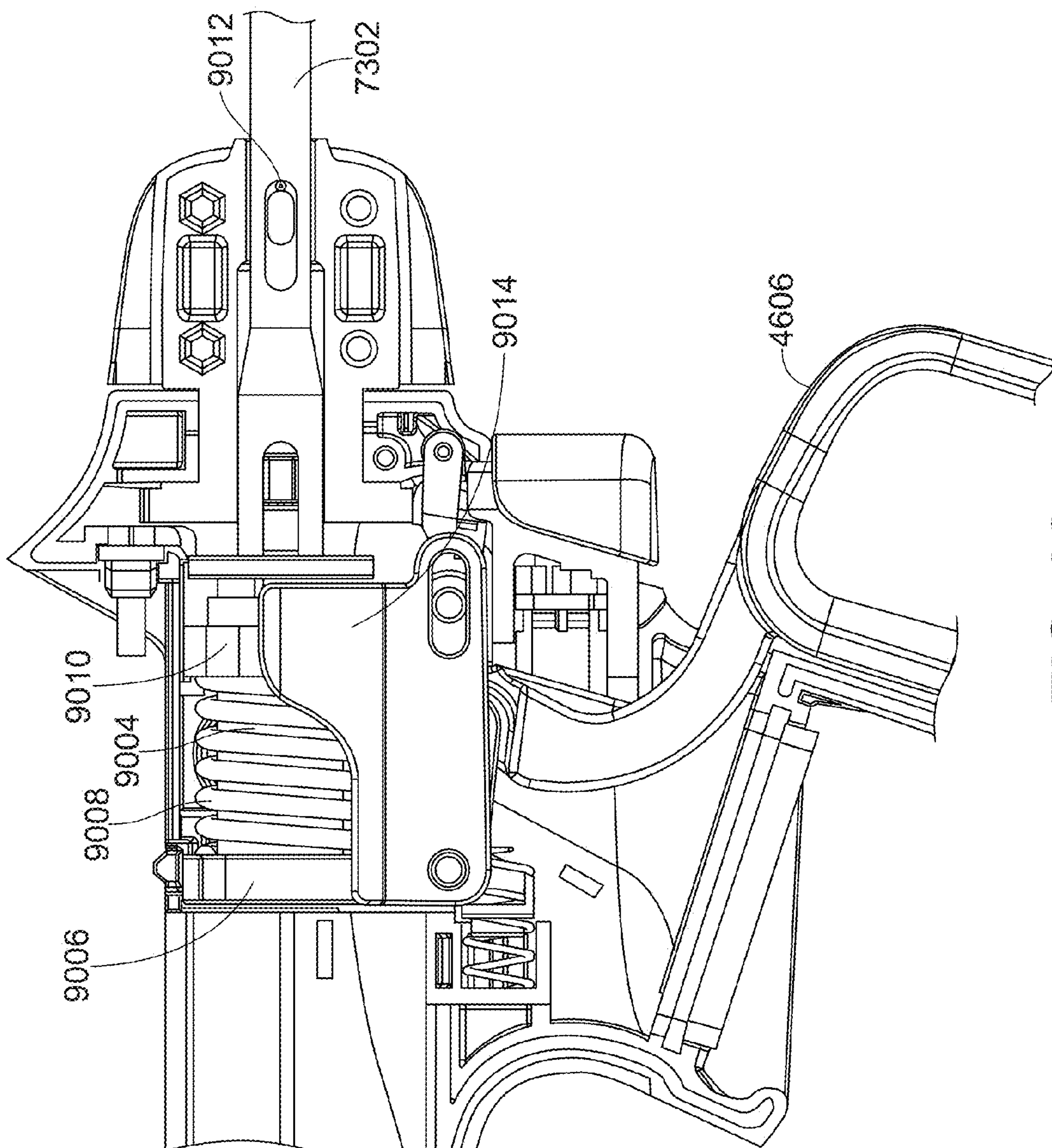


FIG. 92

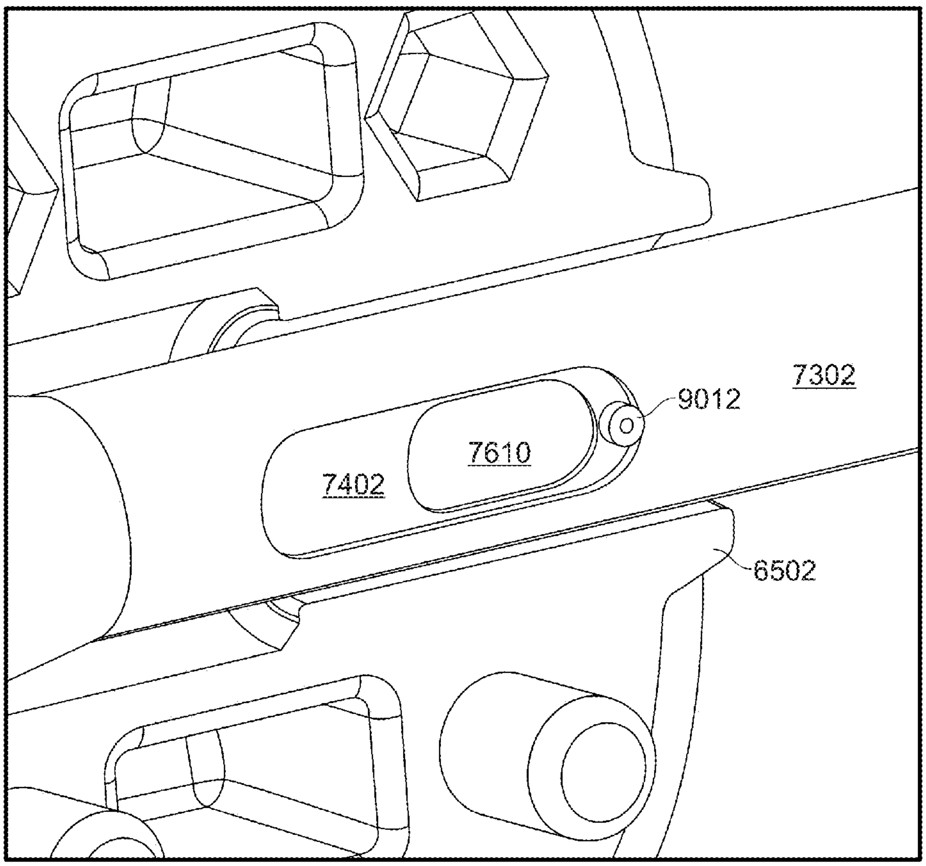


FIG. 93

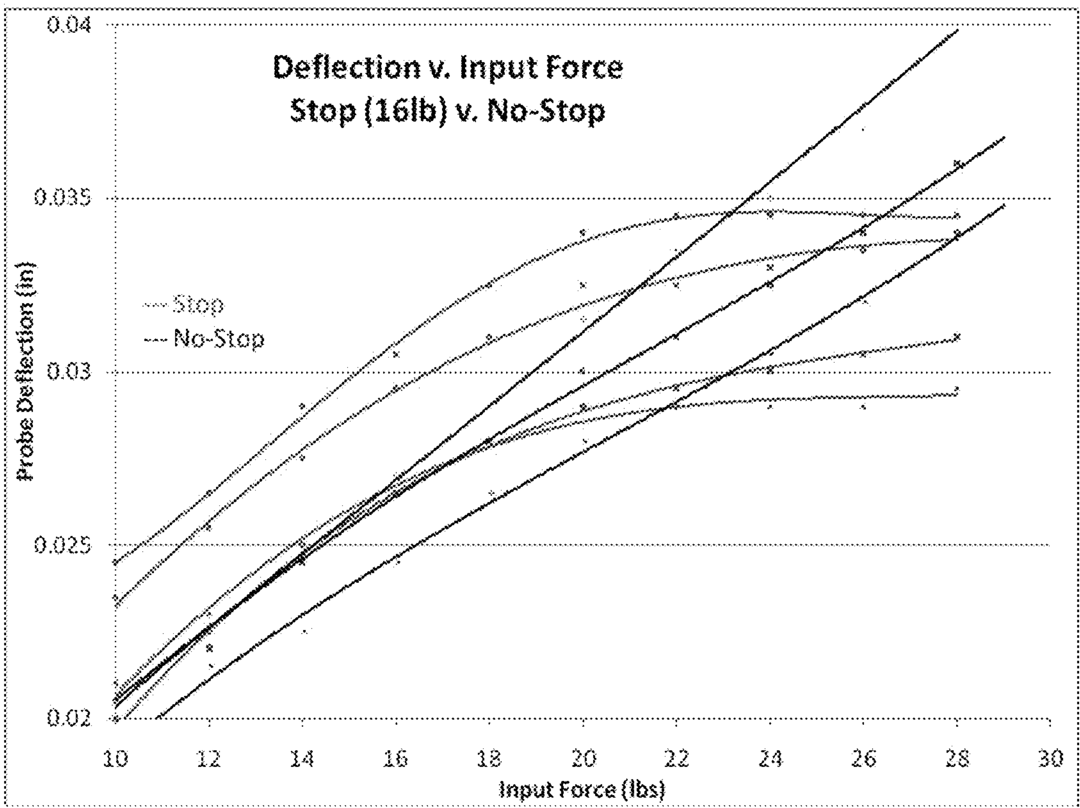

Deflection v. Input Force
Stop (16lb) v. No-Stop
Stop
No-Stop
Probe Deflection (in)
Input Force (lbs)
0.04
0.035
0.03
0.025
0.02
10
12
14
16
18
20
22
24
26
28
30

FIG. 94

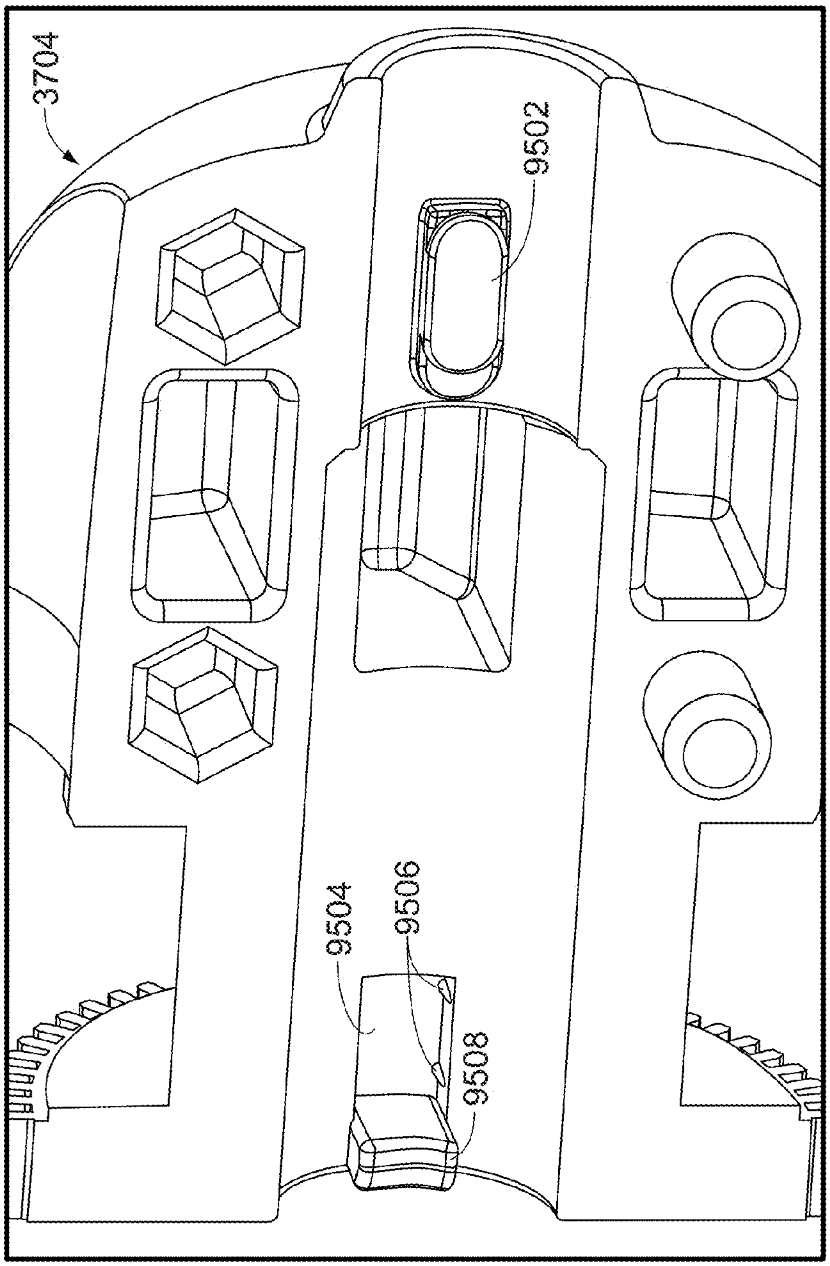


FIG. 95

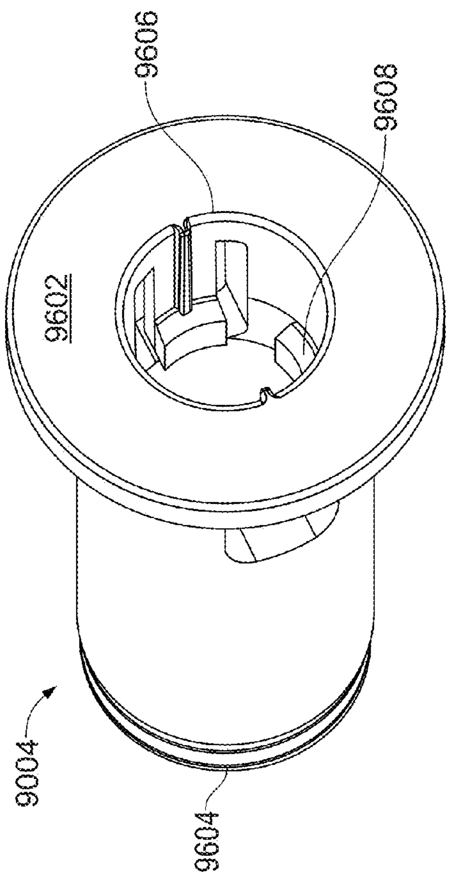

9606
9608
9602
9004
9604

FIG. 96

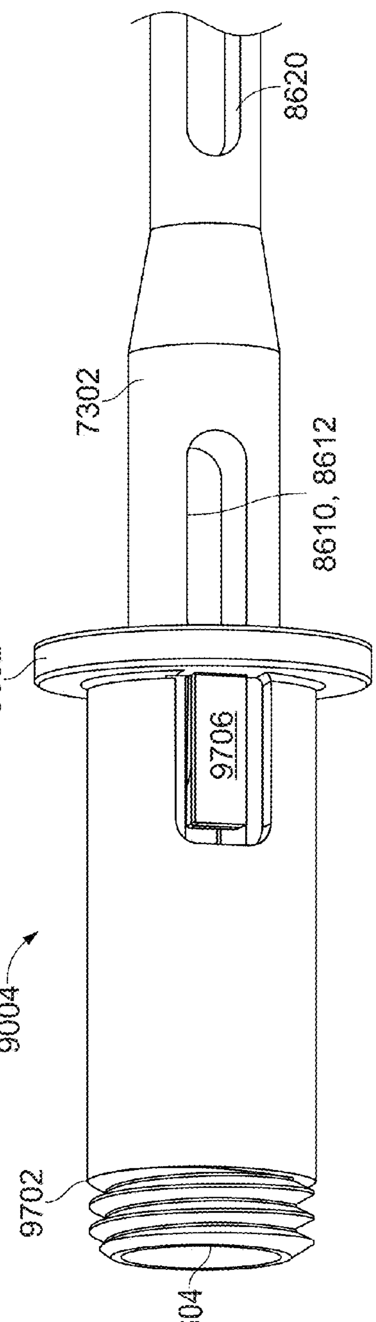

8620
7302
8610, 8612
9602
9706
9004
9702
9604

FIG. 97

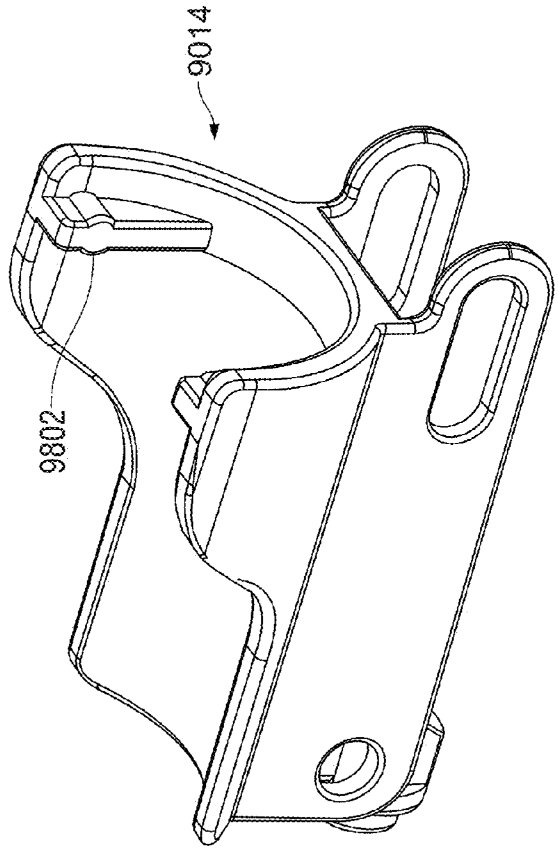


FIG. 98

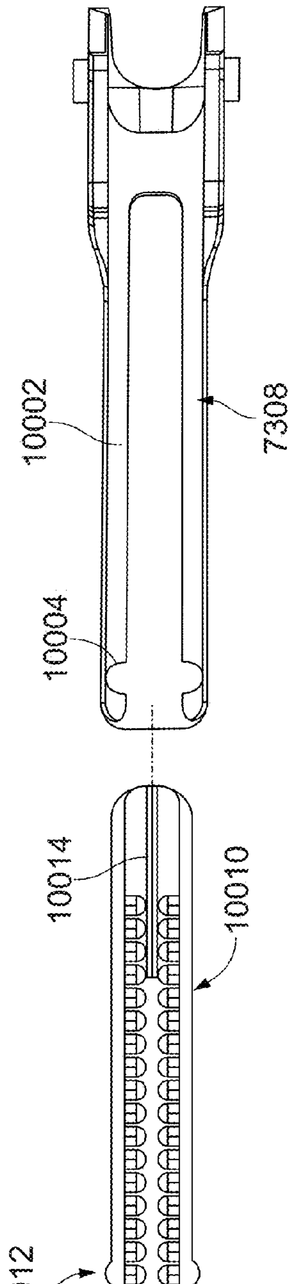


FIG. 100

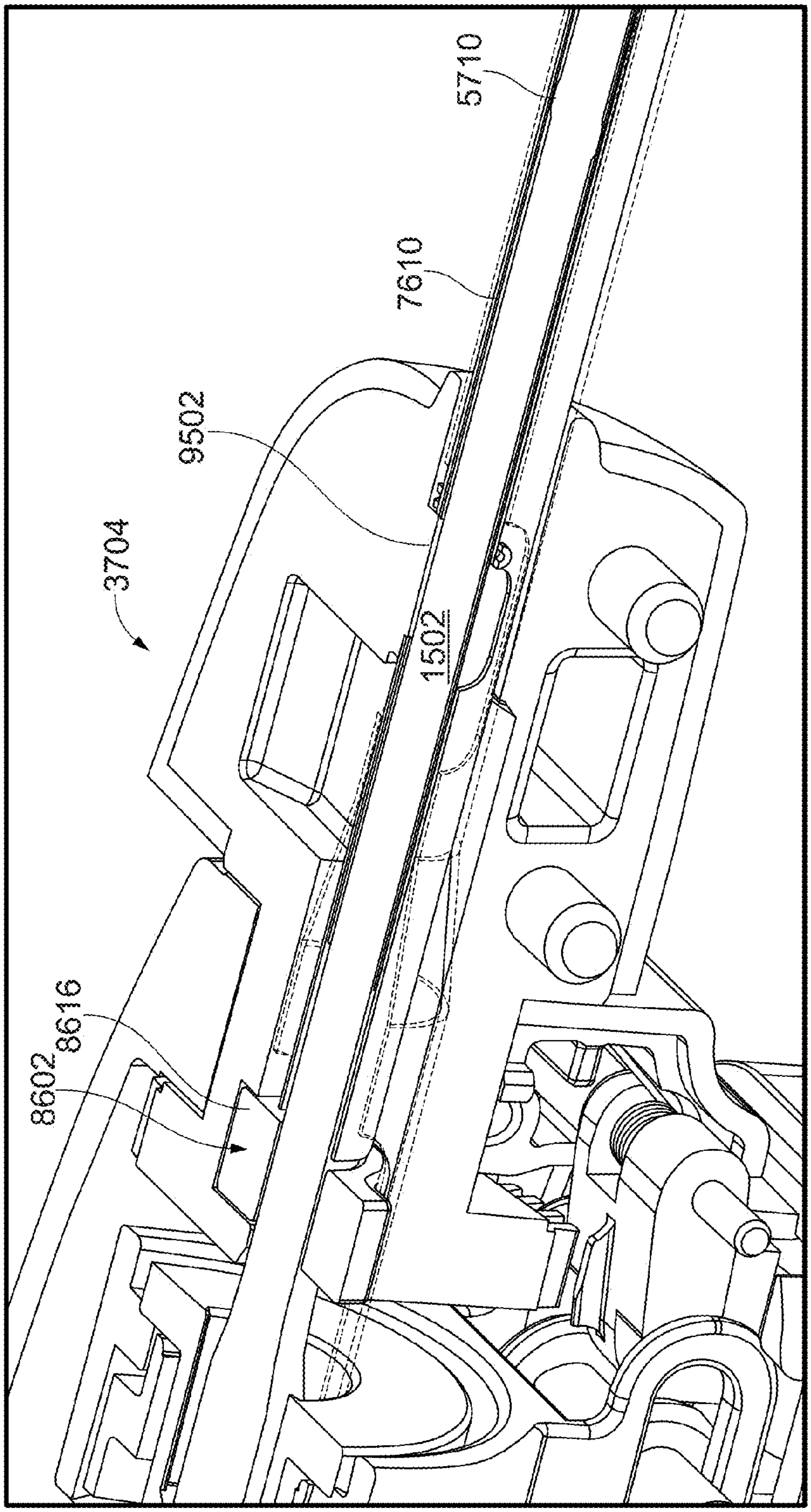


FIG. 99

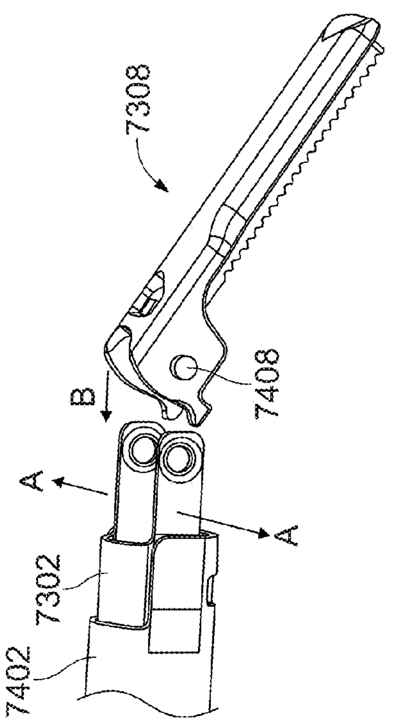


FIG. 101

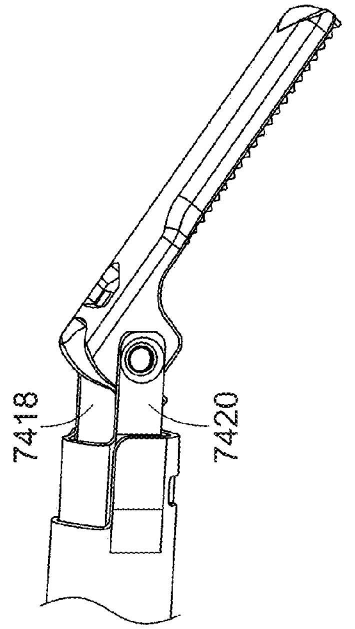


FIG. 102

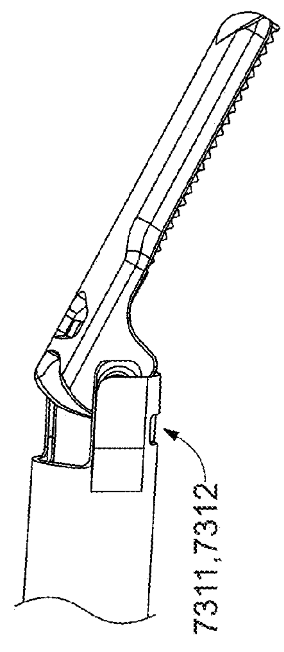


FIG. 103

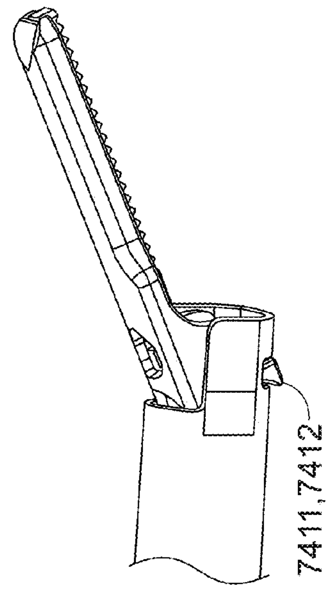


FIG. 104

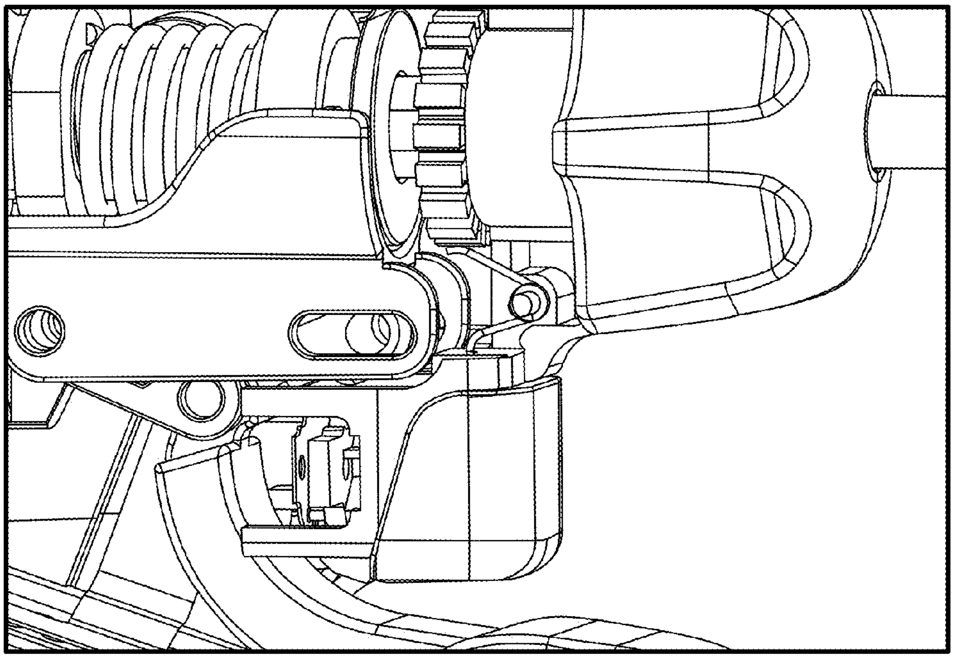


FIG. 105

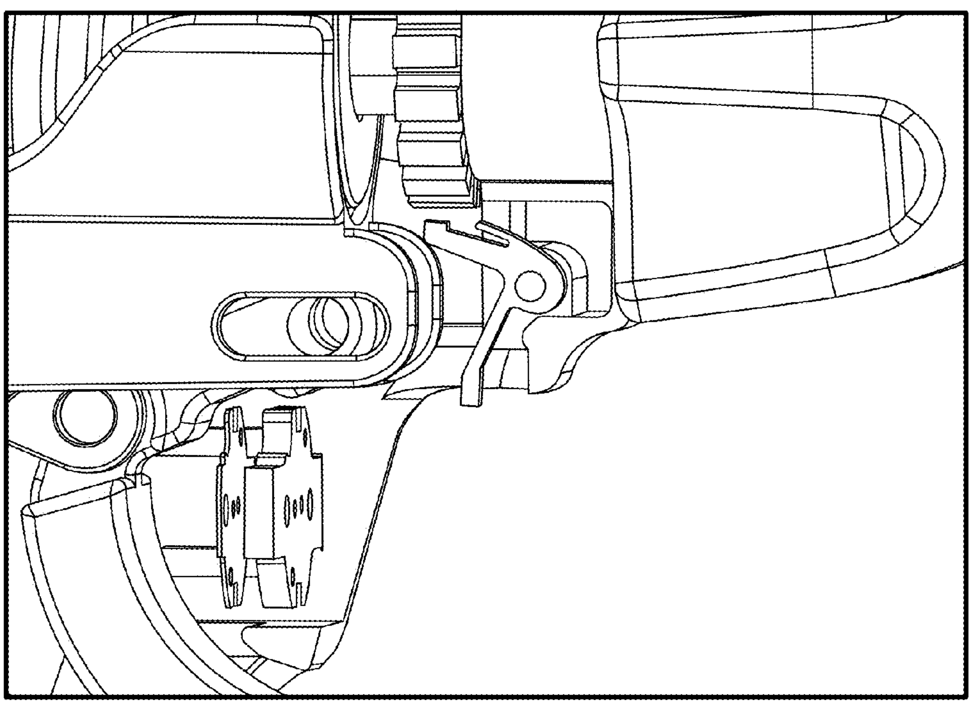


FIG. 106

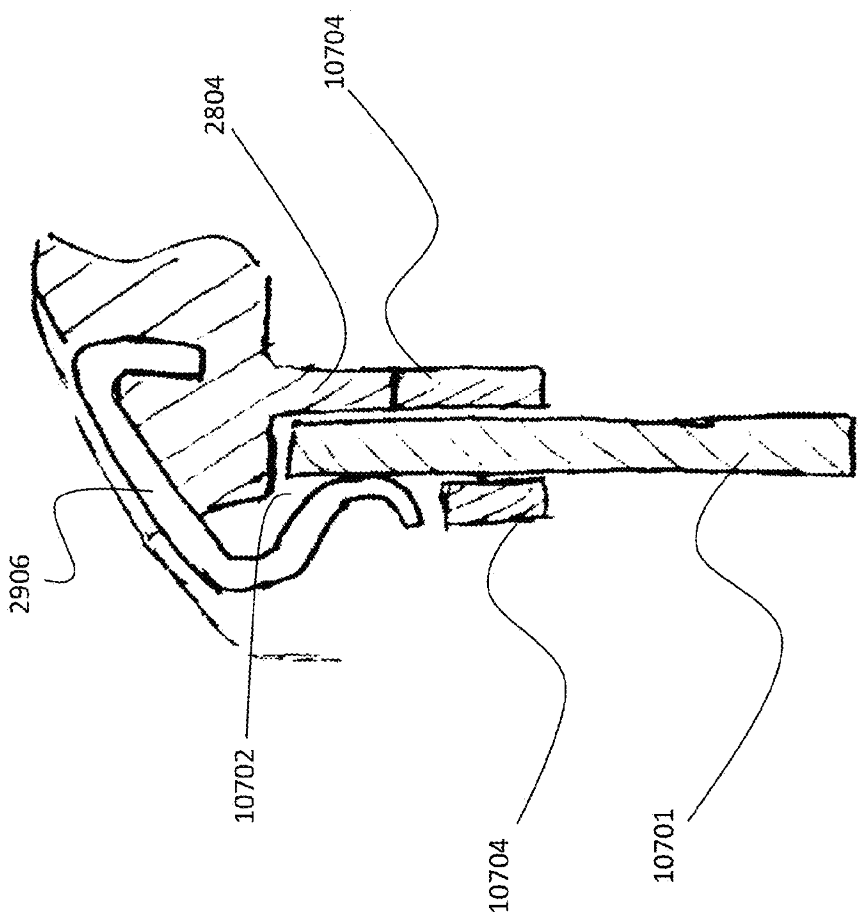


FIG. 107

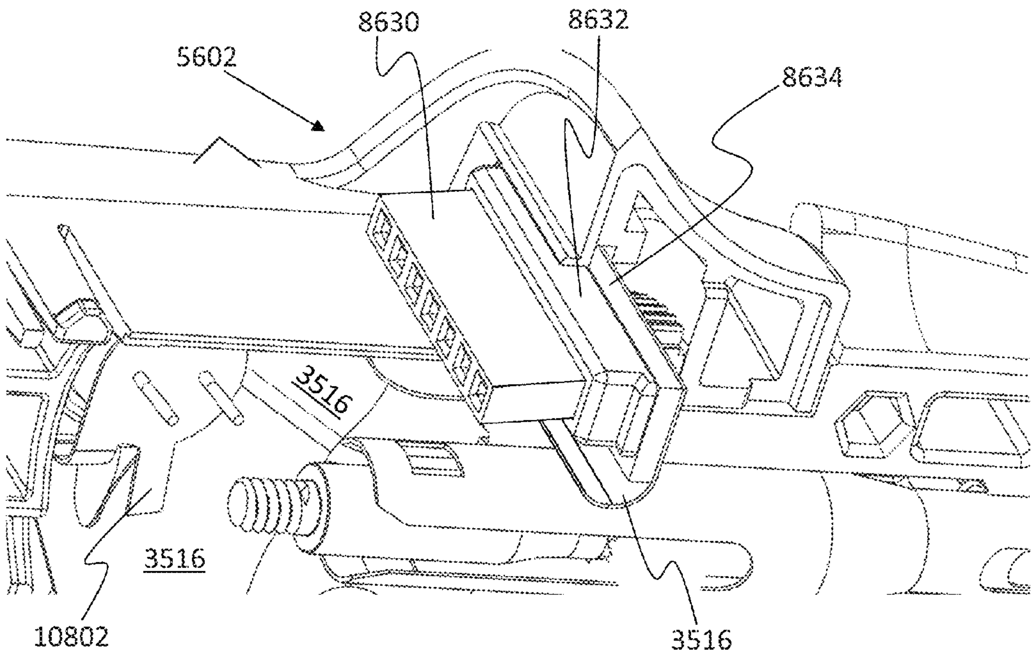


FIG. 108

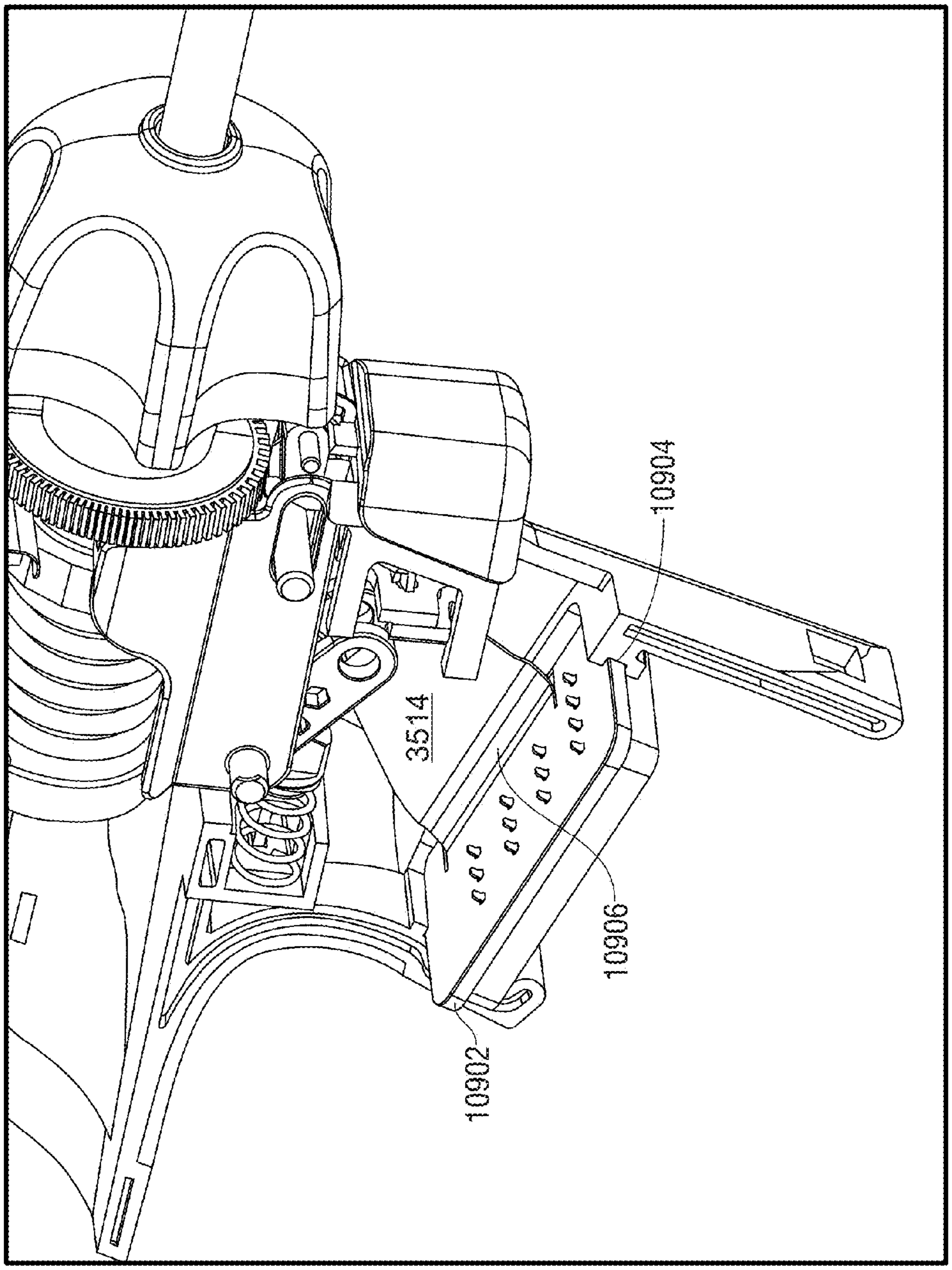


FIG. 109

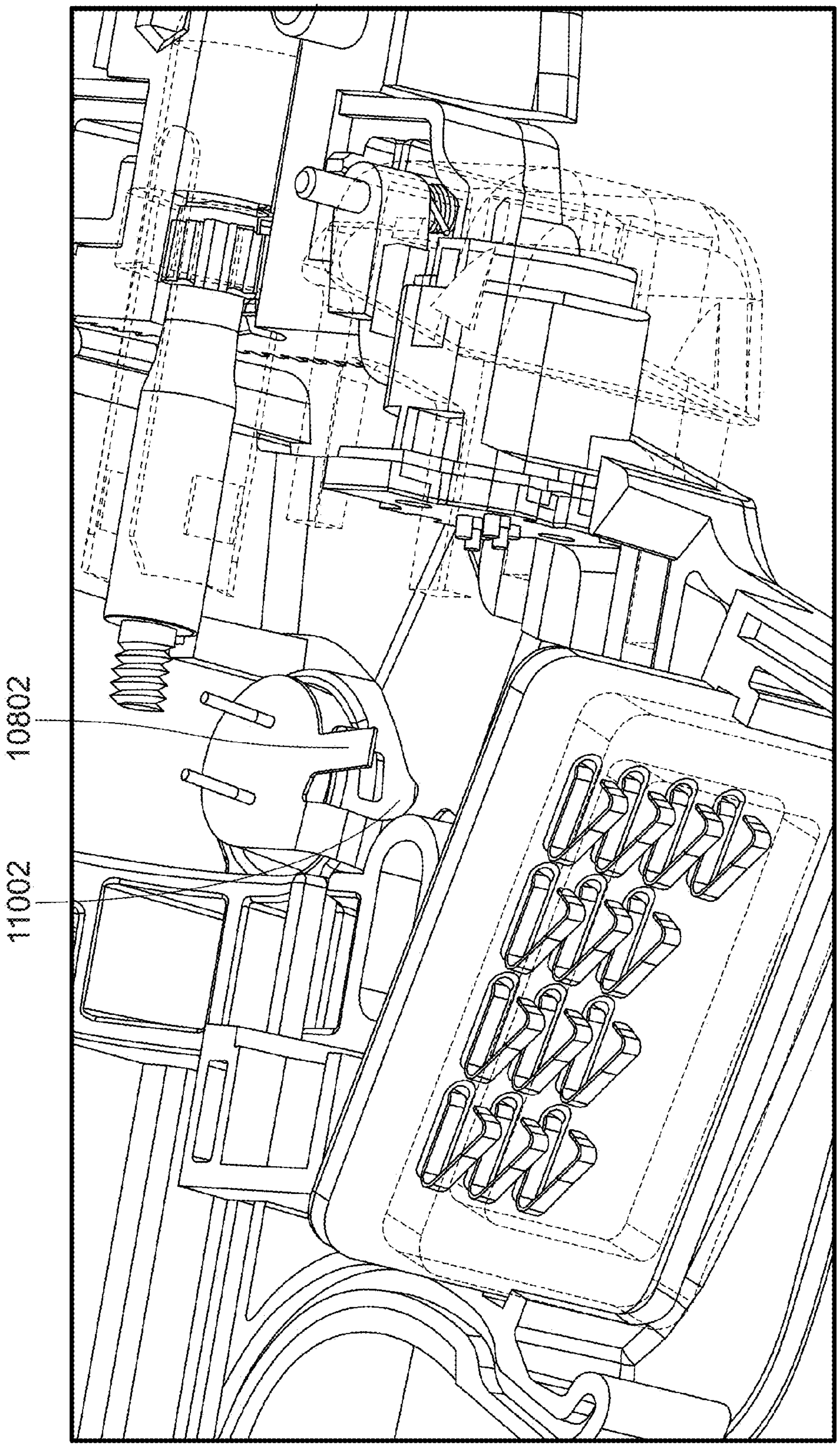


FIG. 110

BATTERY-POWERED HAND-HELD ULTRASONIC SURGICAL CAUTERY CUTTING DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application:

is a divisional of U.S. patent application Ser. No. 13/307,750, filed on Nov. 30, 2011 (which application claims the priority, under 35 U.S.C. §119, of U.S. Provisional Patent Application Ser. No. 61/476,022, filed Apr. 15, 2011);

is a continuation-in-part of U.S. patent application Ser. No. 13/215,971, filed on Aug. 23, 2011 (which application claims the priority, under 35 U.S.C. §119, of U.S. Provisional Patent Application Ser. No. 61/376,983, filed Aug. 25, 2010);

is a continuation-in-part of U.S. patent application Ser. No. 13/022,707, filed on Feb. 8, 2011, now U.S. Pat. No. 8,663,262;

is a continuation-in-part of U.S. patent application Ser. No. 13/022,743, filed on Feb. 8, 2011, now U.S. Pat. No. 8,439,939;

is a continuation-in-part of U.S. patent application Ser. No. 12/868,505, filed on Aug. 25, 2010, now U.S. Pat. No. 8,338,726 (which application claims priority, under 35 U.S.C. §119, to U.S. Provisional Application Ser. No. 61/236,934, filed on Aug. 26, 2009);

is a continuation-in-part of U.S. patent application Ser. No. 12/868,545, filed on Aug. 25, 2010, now U.S. Pat. No. 8,334,468 (which application claims priority, under 35 U.S.C. §119, to U.S. Provisional Application Ser. No. 61/236,934, filed on Aug. 26, 2009);

is a continuation-in-part of U.S. patent application Ser. No. 13/655,522, filed on Oct. 19, 2012, now U.S. Pat. No. 8,497,436;

is a continuation-in-part of U.S. patent application Ser. No. 13/655,532, filed on Oct. 19, 2012, now U.S. Pat. No. 8,502,091;

is a continuation-in-part of U.S. patent application Ser. No. 13/655,557, filed on Oct. 19, 2012, now U.S. Pat. No. 8,497,437;

is a continuation-in-part of U.S. patent application Ser. No. 13/655,571, filed on Oct. 19, 2012, now U.S. Pat. No. 8,487,199;

is a continuation-in-part of U.S. patent application Ser. No. 13/901,994, filed on May 24, 2013, now U.S. Pat. No. 8,742,269;

is a continuation-in-part of U.S. patent application Ser. No. 14/231,042, filed on Mar. 31, 2014;

is a continuation-in-part of U.S. patent application Ser. No. 14/607,358, filed on Jan. 28, 2015;

is a continuation-in-part of U.S. patent application Ser. No. 12/547,898, filed on Aug. 26, 2009, now U.S. Pat. No. 8,061,014;

is a continuation-in-part of U.S. patent application Ser. No. 12/547,975, filed on Aug. 26, 2009, now U.S. Pat. No. 8,435,257;

is a continuation-in-part of U.S. patent application Ser. No. 12/547,999, filed on Aug. 26, 2009, now U.S. Pat. No. 8,425,545;

is a continuation-in-part of U.S. patent application Ser. No. 13/072,187, filed on Mar. 25, 2011, now U.S. Pat. No. 8,197,502;

is a continuation-in-part of U.S. patent application Ser. No. 13/072,247, filed on Mar. 25, 2011, now U.S. Pat. No. 8,333,778;

is a continuation-in-part of U.S. patent application Ser. No. 13/072,273, filed on Mar. 25, 2011, now U.S. Pat. No. 8,333,779;

is a continuation-in-part of U.S. patent application Ser. No. 13/072,221, filed on Mar. 25, 2011, now U.S. Pat. No. 8,236,020;

is a continuation-in-part of U.S. patent application Ser. No. 13/072,309, filed on Mar. 25, 2011, now U.S. Pat. No. 8,372,101;

is a continuation-in-part of U.S. patent application Ser. No. 13/072,345, filed on Mar. 25, 2011, now U.S. Pat. No. 8,377,085;

is a continuation-in-part of U.S. patent application Ser. No. 13/072,373, filed on Mar. 25, 2011, now U.S. Pat. No. 8,418,349;

is a continuation-in-part of U.S. patent application Ser. No. 13/465,820, filed on May 7, 2012;

is a continuation-in-part of U.S. patent application Ser. No. 13/539,694, filed on Jul. 2, 2012;

is a continuation-in-part of U.S. patent application Ser. No. 13/873,958, filed on Apr. 30, 2013;

is a continuation-in-part of U.S. patent application Ser. No. 13/874,010, filed on Apr. 30, 2013;

is a continuation-in-part of U.S. patent application Ser. No. 12/266,101, filed on Nov. 6, 2008, now U.S. Pat. No. 8,419,757 (which application claims priority to U.S. Provisional Application Ser. Nos. 60/991,829, filed on Dec. 3, 2007; 60/992,498, filed on Dec. 5, 2007; 61/019,888, filed on Jan. 9, 2008; 61/045,475, filed on Apr. 16, 2008; 61/048,809, filed on Apr. 29, 2008; and 61/081,885, filed on Jul. 18, 2008);

is a continuation-in-part of U.S. patent application Ser. No. 12/266,146, filed on Nov. 6, 2008, now U.S. Pat. No. 8,419,758 (which application claims priority to U.S. Provisional Application Ser. Nos. 60/991,829, filed on Dec. 3, 2007; 60/992,498, filed on Dec. 5, 2007; 61/019,888, filed on Jan. 9, 2008; 61/045,475, filed on Apr. 16, 2008; 61/048,809, filed on Apr. 29, 2008; and 61/081,885, filed on Jul. 18, 2008);

is a continuation-in-part of U.S. patent application Ser. No. 12/266,226, filed on Nov. 6, 2008 (which application claims priority to U.S. Provisional Application Ser. Nos. 60/991,829, filed on Dec. 3, 2007; 60/992,498, filed on Dec. 5, 2007; 61/019,888, filed on Jan. 9, 2008; 61/045,475, filed on Apr. 16, 2008; 61/048,809, filed on Apr. 29, 2008; and 61/081,885, filed on Jul. 18, 2008);

is a continuation-in-part of U.S. patent application Ser. No. 12/266,252, filed on Nov. 6, 2008 (which application claims priority to U.S. Provisional Application Ser. Nos. 60/991,829, filed on Dec. 3, 2007; 60/992,498, filed on Dec. 5, 2007; 61/019,888, filed on Jan. 9, 2008; 61/045,475, filed on Apr. 16, 2008; 61/048,809, filed on Apr. 29, 2008; and 61/081,885, filed on Jul. 18, 2008);

is a continuation-in-part of U.S. patent application Ser. No. 12/266,320, filed on Nov. 6, 2008, now U.S. Pat. No. 8,403,948 (which application claims priority to U.S. Provisional Application Ser. Nos. 60/991,829, filed on Dec. 3, 2007; 60/992,498, filed on Dec. 5, 2007; 61/019,888, filed on Jan. 9, 2008; 61/045,475, filed on Apr. 16, 2008; 61/048,809, filed on Apr. 29, 2008; and 61/081,885, filed on Jul. 18, 2008);

is a continuation-in-part of U.S. patent application Ser. No. 12/266,664, filed on Nov. 7, 2008, now U.S. Pat. No. 8,372,099 (which application claims priority to U.S.

Provisional Application Ser. Nos. 60/991,829, filed on Dec. 3, 2007; 60/992,498, filed on Dec. 5, 2007; 61/019,888, filed on Jan. 9, 2008; 61/045,475, filed on Apr. 16, 2008; 61/048,809, filed on Apr. 29, 2008; and 61/081,885, filed on Jul. 18, 2008);

is a continuation-in-part of U.S. patent application Ser. No. 12/269,544, filed on Nov. 12, 2008, now U.S. Pat. No. 8,444,662 (which application claims priority to U.S. Provisional Application Ser. Nos. 60/991,829, filed on Dec. 3, 2007; 60/992,498, filed on Dec. 5, 2007; 61/019,888, filed on Jan. 9, 2008; 61/045,475, filed on Apr. 16, 2008; 61/048,809, filed on Apr. 29, 2008; and 61/081,885, filed on Jul. 18, 2008)

is a continuation-in-part of U.S. patent application Ser. No. 12/269,629, filed on Nov. 12, 2008, now U.S. Pat. No. 8,403,949 (which application claims priority to U.S. Provisional Application Ser. Nos. 60/991,829, filed on Dec. 3, 2007; 60/992,498, filed on Dec. 5, 2007; 61/019,888, filed on Jan. 9, 2008; 61/045,475, filed on Apr. 16, 2008; 61/048,809, filed on Apr. 29, 2008; and 61/081,885, filed on Jul. 18, 2008); and

is a continuation-in-part of U.S. patent application Ser. No. 12/270,146, filed on Nov. 13, 2008, now U.S. Pat. No. 8,403,950 (which application claims priority to U.S. Provisional Application Ser. Nos. 60/991,829, filed on Dec. 3, 2007; 60/992,498, filed on Dec. 5, 2007; 61/019,888, filed on Jan. 9, 2008; 61/045,475, filed on Apr. 16, 2008; 61/048,809, filed on Apr. 29, 2008; and 61/081,885, filed on Jul. 18, 2008),

the entire disclosures of which are all hereby incorporated by reference in their entireties.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to an ultrasonic cutting device and, more particularly, relates to a battery-powered, hand-held, ultrasonic surgical cautery cutting device.

2. Description of the Related Art

Ultrasonic instruments are effectively used in the treatment of many medical conditions, such as removal of tissue and cauterization of vessels. Cutting instruments that utilize ultrasonic waves generate vibrations with an ultrasonic transducer along a longitudinal axis of a cutting blade. By placing a resonant wave along the length of the blade, high-speed longitudinal mechanical movement is produced at the end of the blade. These instruments are advantageous because the mechanical vibrations transmitted to the end of the blade are very effective at cutting organic tissue and, simultaneously, coagulating the tissue using the heat energy produced by the ultrasonic frequencies. Such instruments are particularly well suited for use in minimally invasive procedures, such as endoscopic or laparoscopic procedures, where the blade is passed through a trocar to reach the surgical site.

For each kind of cutting blade (e.g., length, material, size), there are one or more (periodic) driving signals that produce a resonance along the length of the blade. Resonance results in movement of the blade tip, which can be optimized for improved performance during surgical procedures. However, producing an effective cutting-blade driving signal is not a trivial task. For instance, the frequency, current, and voltage applied to the cutting tool must all be controlled dynamically, as these parameters change with the varying load placed on the blade and with temperature differentials that result from use of the tool.

FIG. **1** shows a block schematic diagram of a prior-art circuit used for applying ultrasonic mechanical movements to an end effector. The circuit includes a power source **102**, a control circuit **104**, a drive circuit **106**, a matching circuit **108**, a transducer **110**, and also includes a handpiece **112**, and a waveguide **114** secured to the handpiece **112** (diagrammatically illustrated by a dashed line) and supported by an outer, tubular cannula **120**. The waveguide **114** terminates into a blade **116** at a distal end. A clamping mechanism **118**, is part of the overall end effector and exposes and enables the blade portion **116** of the waveguide **114** to make contact with tissue and other substances. Commonly, the clamping mechanism **118** is a pivoting arm that acts to grasp or clamp onto tissue between the arm and the blade **116**. However, in some devices, the clamping mechanism **118** is not present.

The drive circuit **106** produces a high-voltage self-oscillating signal. The high-voltage output of the drive circuit **106** is fed to the matching circuit **108**, which contains signal-smoothing components that, in turn, produce a driving signal (wave) that is fed to the transducer **110**. The oscillating input to the transducer **110** causes the mechanical portion of the transducer **110** to move back and forth at a magnitude and frequency that sets up a resonance along the waveguide **114**. For optimal resonance and longevity of the resonating instrument and its components, the driving signal applied to the transducer **110** should be as smooth a sine wave as can practically be achieved. For this reason, the matching circuit **108**, the transducer **110**, and the waveguide **114** are selected to work in conjunction with one another and are all frequency sensitive with and to each other; this can be referred to as being matched or tuned.

Because a relatively high-voltage (e.g., 100 V or more) is required to drive a typical piezoelectric transducer **110**, the power source that is available and is used in all prior-art ultrasonic cutting devices is an electric mains (e.g., a wall outlet) of, typically, up to 15 A, 120 VAC. Therefore, all known ultrasonic surgical cutting devices resemble that shown in FIGS. **1** and **2** and utilize a countertop box **202** with an electrical cord **204** to be plugged into the electrical mains **206** for supply of power. Resonance is maintained by a phase locked loop (PLL), which creates a closed loop between the output of the matching circuit **108** and the drive circuit **106**. For this reason, in prior art devices, the countertop box **202** always has contained all of the drive and control electronics **104**, **106** and the matching circuit(s) **108**. A typical retail price for such boxes is in the thousands of dollars.

A supply cord **208** delivers a sinusoidal waveform from the box **202** to the transducer **110** within the handpiece **112** and, thereby, to the waveguide **114**. The prior art devices present a great disadvantage because the cord **208** has a length, size, and weight that restricts the mobility of the operator/surgeon. The cord **208** creates a tether for the operator and presents an obstacle for the operator and those around him/her during any surgical procedure using the handpiece **112**. In addition, the cord must be shielded and durable and, therefore, is very expensive. Finally, because the box **202** is not sterilized, both the box **202** and the supply cord **208** must be cleaned and maintained in a sterile condition for use in a surgical environment.

Another disadvantage exists in the prior art due to the frequency sensitivity of the matching circuit **108**, the transducer **110**, and the waveguide **114**. By having a phase-locked-loop feedback circuit between the output of the matching circuit **108** and the drive circuit **104**, the matching circuit **108** has always been located in the box **202**, near the drive circuit **108**, and separated from the transducer **110** by the length of the supply cord **208**. This architecture introduces transmission losses and electrical parasitics, which are common products of ultrasonic-frequency transmissions.

In addition, prior-art devices attempt to maintain resonance at varying waveguide **114** load conditions by monitoring and maintaining a constant current applied to the transducer (when operating with series resonance). However, without knowing the specific load conditions, the only predictable relationship between current applied to the transducer **110** and amplitude is at resonance (in some instances herein, amplitude is sometimes referred to as displacement when the term relates to the mechanical output). Therefore, despite a constant current being applied, the amplitude of the wave along the waveguide **114** may not be constant across all frequencies. When prior art devices are under load, therefore, operation of the waveguide **114** is not guaranteed to be at resonance and, because only the current is being monitored and held constant, the amount of movement on the waveguide **114** can vary greatly. For this reason, maintaining constant current is not an effective way of maintaining a constant movement of the waveguide **114**.

Furthermore, in the prior art, handpieces **112** and transducers **110** are replaced after a finite number of uses, but the box **202**, which is vastly more expensive than the handpiece **112**, is not replaced. As such, introduction of new, replacement handpieces **112** and transducers **110** frequently causes a mismatch between the frequency-sensitive components (**108**, **110**, and **112**), thereby disadvantageously altering the frequency introduced to the waveguide **114**. The only way to avoid such mismatches is for the prior-art circuits to restrict themselves to precise frequencies. This precision brings with it a significant increase in cost.

Therefore, a need exists to overcome the problems associated with the prior art, for example, those discussed above.

SUMMARY OF THE INVENTION

Briefly, in accordance with exemplary embodiments, the present invention includes a battery-powered device that produces high frequency mechanical motion at the end of a waveguide for performing useful work, specifically, to cut and seal tissue during surgery. A piezoelectric transducer is used to convert electrical energy into the mechanical energy that produces the motion at the end of the waveguide. Particularly, when the transducer and waveguide are driven at their composite resonant frequency, a large amount of mechanical motion is produced. The circuit components of the present invention include, among others, a battery power supply, a control circuit, a drive circuit, and a matching circuit—all located within a handpiece of the ultrasonic cutting device and all operating and generating waveforms from battery voltages. The components are selected to convert electrical energy from the battery power supply into a high voltage AC waveform that drives the transducer. Ideally, the frequency of this waveform is substantially the same as the resonant frequency of the waveguide and transducer. The magnitude of the waveform is selected to be a value that produces the desired amount of mechanical motion.

Advantageously, the present invention, according to several embodiments, allows components of the device to be removed, replaced, serviced, and/or interchanged. Some components are "disposable," which, as used herein, means that the component is used for only one procedure and is then discarded. Still other components are "reusable," which, as used herein, means that the component can be sterilized according to standard medical procedures and then used for at least a second time. As will be explained, other components are provided with intelligence that allows them to recognize the device to which they are attached and to alter their function or performance depending on several factors.

The invention provides a cordless hand-held ultrasonic cautery cutting device that overcomes the hereinafore-mentioned disadvantages of the heretofore-known devices and methods of this general type and that allows disposal of inexpensive components but permits advantageous reuse of costlier components that are significantly cheaper than prior art reusable components.

Although the invention is illustrated and described herein as embodied in a cordless, battery-powered, hand-held, ultrasonic, surgical, cautery cutting device, it is, nevertheless, not intended to be limited to the details shown because various modifications and structural changes may be made therein without departing from the spirit of the invention and within the scope and range of equivalents of the claims. Additionally, well-known elements of exemplary embodiments of the invention will not be described in detail or will be omitted so as not to obscure the relevant details of the invention.

While the specification concludes with claims defining the features of the invention that are regarded as novel, it is believed that the invention will be better understood from a consideration of the following description in conjunction with the drawing figures, in which like reference numerals are carried forward. Accordingly, the apparatus components and method steps have been represented where appropriate by conventional symbols in the drawings, showing only those specific details that are pertinent to understanding the embodiments of the present invention so as not to obscure the disclosure with details that will be readily apparent to those of ordinary skill in the art having the benefit of the description herein. The figures of the drawings are not drawn to scale.

Other features that are considered as characteristic for the invention are set forth in the appended claims. As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which can be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one of ordinary skill in the art to variously employ the present invention in virtually any appropriately detailed structure. Further, the terms and phrases used herein are not intended to be limiting; but rather, to provide an understandable description of the invention.

DETAILED DESCRIPTION OF THE DRAWINGS

The accompanying figures, where like reference numerals refer to identical or functionally similar elements throughout the separate views and which together with the detailed description below are incorporated in and form part of the specification, serve to further illustrate various embodiments and to explain various principles and advantages all in accordance with the present invention.

FIG. **1** is a diagrammatic illustration of components of a prior-art ultrasonic cutting device with separate power, control, drive and matching components in block-diagram form.

FIG. **2** is a diagram illustrating the prior-art ultrasonic cutting device of FIG. **1**.

FIG. **3** is an elevational view of a left side of an ultrasonic surgical cautery assembly in accordance with an exemplary embodiment of the present invention.

FIG. **4** is a perspective view from above a corner of a battery assembly in accordance with an exemplary embodiment of the present invention.

FIG. 5 is an elevational left side view of a transducer and generator ("TAG") assembly in accordance with an exemplary embodiment of the present invention.

FIG. 6 is a schematic block diagram of a cordless, battery-powered, hand-held, ultrasonic, surgical, cautery cutting device in accordance with an exemplary embodiment of the present invention.

FIG. 7 is a schematic block diagram of a battery assembly of the device of FIGS. 3 and 4 in accordance with an exemplary embodiment of the present invention.

FIG. 8 is a schematic block diagram of a handle assembly of the device of FIGS. 3 and 4 in accordance with an exemplary embodiment of the present invention.

FIG. 9 is a schematic block diagram of the transducer and generator assembly of the device of FIGS. 3 to 5 in accordance with an exemplary embodiment of the present invention.

FIG. 10 is a schematic block diagram of the generator of FIG. 9 in accordance with an exemplary embodiment of the present invention.

FIG. 11 is a schematic block diagram of the battery controller of the device of FIGS. 3 and 4 in accordance with an exemplary embodiment of the present invention.

FIG. 12 is a schematic block diagram illustrating an electrical communicating relationship between the battery assembly and the transducer and generator assembly of the device of FIGS. 3 to 5 in accordance with an exemplary embodiment of the present invention.

FIG. 13 is graph illustrating a square waveform input to a matching circuit in accordance with an exemplary embodiment of the present invention.

FIG. 14 is graph illustrating a sinusoidal waveform output from a matching circuit in accordance with an exemplary embodiment of the present invention.

FIG. 15 is a diagrammatic illustration of the affect that a resonant sine wave input to a transducer has on a waveguide of the ultrasonic cutting device in accordance with an exemplary embodiment of the present invention with the sinusoidal pattern shown representing the amplitude of axial motion along the length of the waveguide.

FIG. 16 is a fragmentary, schematic circuit diagram of an elemental series circuit model for a transducer in accordance with an exemplary embodiment of the present invention.

FIG. 17 is a fragmentary, schematic circuit diagram of an inventive circuit with the circuit of FIG. 16 and is useful for monitoring a motional current of a transducer in accordance with an exemplary embodiment of the present invention.

FIG. 18 is a fragmentary, schematic circuit diagram of an elemental parallel circuit model of a transducer in accordance with an exemplary embodiment of the present invention.

FIG. 19 is fragmentary, schematic circuit diagram of an inventive circuit with the circuit of FIG. 18 and is useful for monitoring the motional current of a transducer in accordance with an exemplary embodiment of the present invention.

FIG. 20 is a fragmentary, schematic circuit diagram of an inventive circuit with the circuit of FIG. 16 and is useful for monitoring the motional current of a transducer in accordance with an exemplary embodiment of the present invention.

FIG. 21 is a fragmentary, schematic circuit diagram of an inventive circuit with the circuit of FIG. 18 and is useful for monitoring the motional voltage of a transducer in accordance with an exemplary embodiment of the present invention.

FIG. 22 is a schematic circuit diagram modeling a direct digital synthesis technique implemented in accordance with an exemplary embodiment of the present invention.

FIG. 23 is a graph illustrating an exemplary direct output of a digital-to-analog converter (DAC) positioned above a filtered output of the DAC in accordance with an exemplary embodiment of the present invention.

FIG. 24 is a graph illustrating an exemplary direct output of a digital-to-analog converter (DAC) with a tuning word shorter than the tuning word used to produce the graph of FIG. 23 positioned above a filtered output of the DAC using the same shortened tuning word in accordance with an exemplary embodiment of the present invention.

FIG. 25 is a graph illustrating an exemplary direct output of a digital-to-analog converter (DAC) with a tuning word longer than the tuning word used to produce the graph of FIG. 23 positioned above a filtered output of the DAC using the longer tuning word in accordance with an exemplary embodiment of the present invention.

FIG. 26 is block circuit diagram of exemplary components comprising the current control loop in accordance with an exemplary embodiment of the present invention.

FIG. 27 is a block circuit diagram of the device of FIG. 3 in accordance with an exemplary embodiment of the present invention.

FIG. 28 is a perspective view from above the front of the battery assembly of FIG. 4 in accordance with an exemplary embodiment of the present invention.

FIG. 29 is a fragmentary, perspective view from a left side of the battery assembly of FIG. 4 with one half of the shell removed exposing an underside of a multi-lead battery terminal and an interior of the remaining shell half in accordance with an exemplary embodiment of the present invention.

FIG. 30 is a fragmentary, perspective view from a right side of the battery assembly of FIG. 4 with one half of the shell removed exposing a circuit board connected to the multi-lead battery terminal in accordance with an exemplary embodiment of the present invention.

FIG. 31 is an elevated perspective view of the battery assembly of FIG. 4 with both halves of the shell removed exposing battery cells coupled to multiple circuit boards which are coupled to the multi-lead battery terminal in accordance with an exemplary embodiment of the present invention.

FIG. 32 is an elevated perspective view of the battery assembly shown in FIG. 31 with one half of the shell in place in accordance with an exemplary embodiment of the present invention.

FIG. 33 is an elevated perspective view of the battery assembly of FIG. 4 showing a catch located on a rear side of the battery assembly in accordance with an exemplary embodiment of the present invention.

FIG. 34 is an underside perspective view of the handle assembly of FIG. 3 exposing a multi-lead handle terminal assembly and a receiver for mating with the battery assembly of FIG. 4 in accordance with an exemplary embodiment of the present invention.

FIG. 35 is a close-up underside perspective view of the handle assembly of FIG. 3 exposing a multi-lead handle terminal assembly and a receiver for mating with the battery assembly of FIG. 4 in accordance with an exemplary embodiment of the present invention.

FIG. 36 is an underside perspective view illustrating an initial mating connection between the handle assembly and the battery assembly in accordance with an exemplary embodiment of the present invention.

FIG. 37 is a perspective view of the battery assembly fully connected to the handle assembly in accordance with an exemplary embodiment of the present invention.

FIG. **38** is a close-up perspective view of the exterior surface of the battery assembly of FIG. **4** illustrating a release mechanism for coupling the battery assembly to the handle assembly in accordance with an exemplary embodiment of the present invention.

FIG. **39** is a close-up perspective view of the multi-lead handle terminal assembly in accordance with an exemplary embodiment of the present invention.

FIG. **40** is a close-up perspective view of the ultrasonic surgical cautery assembly of FIG. **1** with one half the shell of the handle assembly removed providing a detailed view of the mating position between the multi-lead handle terminal assembly and the multi-lead handle battery assembly in accordance with an exemplary embodiment of the present invention.

FIG. **41** is a fragmentary, cross-sectional and perspective view of a pressure valve of the battery assembly of FIG. **3** in accordance with an exemplary embodiment of the present invention viewed from a direction inside the battery assembly.

FIG. **42** is a fragmentary, cross-sectional view of the pressure valve of FIG. **41** viewed from a side of the valve.

FIG. **43** is a perspective view of the pressure valve of FIG. **41** separated from the battery assembly.

FIG. **44** is a graph illustrating pressure states of the pressure valve of FIG. **41** in accordance with an exemplary embodiment of the present invention.

FIG. **45** is an elevational exploded view of the left side of the ultrasonic surgical cautery assembly of FIG. **3** showing the left shell half removed from the battery assembly and the left shell half removed from the handle assembly in accordance with an exemplary embodiment of the present invention.

FIG. **46** is an elevational right-hand view of the handle assembly of FIG. **3** with the right shell half removed showing controls in accordance with an exemplary embodiment of the present invention.

FIG. **47** is elevational close-up view of the handle assembly of FIG. **3** with the left shell half removed showing the trigger mechanism of FIG. **46** in accordance with an exemplary embodiment of the present invention.

FIG. **48** is an elevational close-up view of a two-stage switch in the handle assembly activated by the button of FIG. **46** in accordance with an exemplary embodiment of the present invention.

FIG. **49** is an elevational view of an example of a two-stage switch of FIG. **48** in accordance with an exemplary embodiment of the present invention.

FIG. **50** is an elevational side view of the TAG of FIG. **3** in accordance with an exemplary embodiment of the present invention.

FIG. **51** is an elevational underside view of the TAG of FIG. **50** in accordance with an exemplary embodiment of the present invention.

FIG. **52** is an elevational upper view of the TAG of FIG. **50** in accordance with an exemplary embodiment of the present invention.

FIG. **53** is an elevational view of the TAG of FIG. **50** with an upper cover removed revealing generator circuitry in accordance with an exemplary embodiment of the present invention.

FIG. **54** is an elevational underside view of the TAG of FIG. **50** with an underside cover removed revealing electrical coupling between the generator and the transducer in accordance with an exemplary embodiment of the present invention.

FIG. **55** is a perspective underside view of the TAG of FIG. **50** with an underside cover of the TAG removed and the transducer cover removed revealing components of the transducer in accordance with an exemplary embodiment of the present invention.

FIG. **56** is an elevational left side view of the handle assembly and the TAG, illustrating a coupling alignment between the handle assembly and the TAG in accordance with an exemplary embodiment of the present invention.

FIG. **57** is an elevational exploded view of the left side of the ultrasonic surgical cautery assembly of FIG. **3** showing the left shell half removed from handle assembly exposing a device identifier communicatively coupled to the multi-lead handle terminal assembly in accordance with an exemplary embodiment of the present invention.

FIG. **58** is a perspective enlarged view of a transducer with the outer shell removed in accordance with an exemplary embodiment of the present invention.

FIG. **59** is a perspective close-up view of the coupling relationship between the catch on the battery assembly and the receiver on the handle assembly as well as the sealing relationship between the multi-lead battery terminal assembly and the multi-lead handle terminal assembly in accordance with an exemplary embodiment of the present invention.

FIG. **60** is a perspective close-up transparent view of the sealing gasket of FIG. **59** in accordance with an exemplary embodiment of the present invention.

FIG. **61** is a perspective partial view of the handle assembly with the right-hand cover half removed, exposing a near-over-centering trigger mechanism in accordance with an exemplary embodiment of the present invention.

FIG. **62** is a perspective partial view of the near-over-centering trigger mechanism of FIG. **61**, with the trigger slightly depressed, in accordance with an exemplary embodiment of the present invention.

FIG. **63** is a perspective partial view of the near-over-centering trigger mechanism of FIG. **61**, with the trigger further depressed, in accordance with an exemplary embodiment of the present invention.

FIG. **64** is a perspective partial view of the near-over-centering trigger mechanism of FIG. **61**, with the trigger fully depressed, in accordance with an exemplary embodiment of the present invention.

FIG. **65** is a perspective fragmentary view of a rotational lockout member and blade adjacent, but not engaging with, a waveguide assembly rotation-prevention wheel, in accordance with an exemplary embodiment of the present invention.

FIG. **66** is a perspective fragmentary view of the rotational lockout member and blade of FIG. **65** engaging the waveguide assembly rotation-prevention wheel in accordance with an exemplary embodiment of the present invention.

FIG. **67** is a perspective fragmentary view of a two-stage button in an undepressed state and in physical communication with the rotational lockout member of FIG. **65** in accordance with an exemplary embodiment of the present invention.

FIG. **68** is a perspective fragmentary view of the two-stage button in a first depressed state and physically engaging the rotational lockout member of FIG. **65** in accordance with an exemplary embodiment of the present invention.

FIG. **69** is a perspective fragmentary view of the two-stage button of FIG. **68** in a second depressed state and fully engaging the rotational lockout member of FIG. **65**, which, in turn, is engaging the waveguide assembly rotation-prevention wheel in accordance with an exemplary embodiment of the present invention.

FIG. **70** is a perspective fragmentary view of a rotational lockout member and dual blades adjacent, but not engaging with, a waveguide assembly rotation-prevention wheel, in accordance with an exemplary embodiment of the present invention.

FIG. **71** is a perspective fragmentary view of the rotational lockout member and dual blades of FIG. **70** engaging the waveguide assembly rotation-prevention wheel in accordance with an exemplary embodiment of the present invention.

FIG. **72** is a process flow diagram illustrating a start-up procedure in accordance with an exemplary embodiment of the present invention.

FIG. **72**A is a process flow diagram illustrating a portion of the start-up procedure in accordance with an exemplary embodiment of the present invention.

FIG. **73** is a fragmentary, enlarged perspective view of an exemplary embodiment of an end effector according to the invention from a distal end with a jaw in an open position.

FIG. **74** is a fragmentary, enlarged perspective view of the end effector of FIG. **73** from below with an outer tube removed.

FIG. **75** is a fragmentary, enlarged cross-sectional and perspective view of the end effector of FIG. **73** from below with the section taken transverse to the jaw-operating plane through the waveguide.

FIG. **76** is a fragmentary, enlarged side cross-sectional view of the end effector of FIG. **73** with the jaw in a partially closed position.

FIG. **77** is a fragmentary, enlarged cross-sectional side view of the end effector of FIG. **73** with the section taken parallel to the jaw-operating plane with the waveguide removed.

FIG. **78** is a fragmentary, enlarged, side elevational view of the end effector of FIG. **73**.

FIG. **79** is a fragmentary, enlarged, side elevational view of the end effector of FIG. **78** with the jaw in a substantially closed position.

FIG. **80** is a fragmentary, enlarged, perspective view of the end effector of FIG. **73** with the jaw in a partially closed position.

FIG. **81** is a fragmentary, enlarged cross-sectional side view of the end effector of FIG. **73** with the section taken in the jaw-operating plane.

FIG. **82** is an enlarged perspective view of a coupling spool of the end effector of FIG. **73**.

FIG. **83** is a fragmentary, enlarged, cross-sectional view of the end effector of FIG. **73** with the section taken orthogonal to the longitudinal axis of the waveguide at a jaw pivot.

FIG. **84** is an enlarged, perspective view of a jaw liner of the end effector of FIG. **73** viewed from below a distal end.

FIG. **85** is an enlarged, cross-sectional and perspective view of a left portion of the jaw liner of FIG. **84** seated within a left portion of the jaw of FIG. **73** viewed from below a proximal end.

FIG. **86** is a fragmentary, enlarged, perspective view of a TAG attachment dock and a waveguide attachment dock of the handle assembly of FIG. **46** with a right half of the handle body, a rotation-prevention wheel, and a spring and bobbin of the jaw force-limiting assembly removed.

FIG. **87** is a fragmentary, enlarged, perspective view of the handle assembly of FIG. **86** with an outer tube removed and only a right half of the rotation-prevention wheel removed.

FIG. **88** is a perspective view of a torque wrench according to an exemplary embodiment of the invention.

FIG. **89** is a fragmentary, enlarged, perspective view of the end effector of FIG. **73** with the jaw in a closed position with liner wear.

FIG. **90** is an elevational right-hand view of the handle assembly of FIG. **3** with the right shell half removed showing controls in accordance with an exemplary embodiment of the present invention with the trigger in an unactuated state.

FIG. **91** is an elevational right-hand view of the handle assembly of FIG. **90** with the trigger in a partially actuated state.

FIG. **92** is an elevational right-hand view of the handle assembly of FIG. **90** with the trigger in a fully actuated state.

FIG. **93** is a fragmentary, enlarged, perspective view of a tube stop assembly in accordance with an exemplary embodiment of the present invention.

FIG. **94** is a graph illustrating blade deflection characteristics associated with the tube stop assembly of FIG. **93**.

FIG. **95** is a perspective side view of half of a spindle assembly according to an exemplary embodiment of the invention.

FIG. **96** is a perspective view of a bobbin portion of a waveguide assembly according to an exemplary embodiment of the invention.

FIG. **97** is a fragmentary, perspective view of the bobbin of FIG. **96** connected to the waveguide.

FIG. **98** is a perspective side view of a yoke of a jaw control assembly according to an exemplary embodiment of the invention.

FIG. **99** is a fragmentary, horizontal cross-sectional view of a proximal portion of the waveguide assembly and a distal portion of the handle according to an exemplary embodiment of the invention.

FIG. **100** is an exploded, bottom perspective view of an alternative exemplary embodiment of a jaw and liner according to the invention.

FIG. **101** is a fragmentary, exploded perspective view of the jaw assembly according to the invention in a first installation step.

FIG. **102** is a fragmentary, exploded perspective view of the jaw assembly according to the invention in a second installation step.

FIG. **103** is a fragmentary, exploded perspective view of the jaw assembly according to the invention in a third installation step.

FIG. **104** is a fragmentary, exploded perspective view of the jaw assembly according to the invention in a fourth installation step.

FIG. **105** is a fragmentary, side perspective view of an alternative exemplary embodiment of a spindle rotation prevention assembly of the handle according to the invention.

FIG. **106** is a fragmentary, side perspective view of another alternative exemplary embodiment of a spindle rotation prevention assembly of the handle according to the invention.

FIG. **107** is a fragmentary, enlarged, cross-sectional view of a portion of the battery assembly of FIG. **4** exposing an underside of a multi-lead battery terminal and an interior of a shell half in accordance with an alternative exemplary embodiment of the present invention in which a card edge connector is used to connect the contacts of the multi-lead battery terminal to one or more circuit boards.

FIG. **108** is a fragmentary, perspective view of an exemplary embodiment of a TAG assembly connector according to the invention.

FIG. **109** is a fragmentary, side perspective view of an exemplary embodiment of a battery connection portion of the flex harness according to the invention.

FIG. **110** is a fragmentary, bottom perspective view of an exemplary embodiment of a buzzer portion of the flex harness according to the invention.

DETAILED DESCRIPTION OF THE EMBODIMENTS

It is to be understood that the disclosed embodiments are merely exemplary of the invention, which can be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure. Further, the terms and phrases used herein are not intended to be limiting; but rather, to provide an understandable description of the invention.

Before the present invention is disclosed and described, it is to be understood that the terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting. In this document, the terms "a" or "an", as used herein, are defined as one or more than one. The term "plurality," as used herein, is defined as two or more than two. The term "another," as used herein, is defined as at least a second or more. The terms "including" and/or "having," as used herein, are defined as comprising (i.e., open language). The term "coupled," as used herein, is defined as connected, although not necessarily directly, and not necessarily mechanically. Relational terms such as first and second, top and bottom, and the like may be used solely to distinguish one entity or action from another entity or action without necessarily requiring or implying any actual such relationship or order between such entities or actions. The terms "comprises," "comprising," or any other variation thereof are intended to cover a non-exclusive inclusion, such that a process, method, article, or apparatus that comprises a list of elements does not include only those elements but may include other elements not expressly listed or inherent to such process, method, article, or apparatus. An element proceeded by "comprises . . . a" does not, without more constraints, preclude the existence of additional identical elements in the process, method, article, or apparatus that comprises the element.

As used herein, the term "about" or "approximately" applies to all numeric values, whether or not explicitly indicated. These terms generally refer to a range of numbers that one of skill in the art would consider equivalent to the recited values (i.e., having the same function or result). In many instances these terms may include numbers that are rounded to the nearest significant figure. In this document, the term "longitudinal" should be understood to mean in a direction corresponding to an elongated direction of the object being described.

It will be appreciated that embodiments of the invention described herein may be comprised of one or more conventional processors and unique stored program instructions that control the one or more processors to implement, in conjunction with certain non-processor circuits and other elements, some, most, or all of the functions of ultrasonic cutting devices described herein. The non-processor circuits may include, but are not limited to, signal drivers, clock circuits, power source circuits, and user input and output elements. Alternatively, some or all functions could be implemented by a state machine that has no stored program instructions, or in one or more application specific integrated circuits (ASICs) or field-programmable gate arrays (FPGA), in which each function or some combinations of certain of the functions are implemented as custom logic. Of course, a combination of these approaches could also be used. Thus, methods and means for these functions have been described herein.

The terms "program," "software application," and the like as used herein, are defined as a sequence of instructions designed for execution on a computer system. A "program," "computer program," or "software application" may include a subroutine, a function, a procedure, an object method, an object implementation, an executable application, an applet, a servlet, a source code, an object code, a shared library/dynamic load library and/or other sequence of instructions designed for execution on a computer system.

The present invention, according to one embodiment, overcomes problems with the prior art by providing a lightweight, hand-held, cordless, battery-powered, surgical cautery cutting device that is powered by and controlled with components that fit entirely within a handle of the device—the set-top box and the shielded cord are entirely eliminated. The hand-held device allows a surgeon to perform ultrasonic cutting and/or cauterizing in any surgical procedure without the need for external power and, particularly, without the presence of cords tethering the surgeon to a stationary object and constricting the range of movement of the surgeon while performing the surgical procedure.

Ultrasonic Surgical Device

Described now is an exemplary apparatus according to one embodiment of the present invention. Referring to FIG. **3**, an exemplary cordless ultrasonic surgical cautery assembly **300** is shown. The inventive assembly **300** can be described as including three main component parts: (1) a battery assembly **301**; (2) a handle assembly **302** with an ultrasonic-cutting-blade-and-waveguide assembly **304** (only a proximal portion of which is illustrated in FIG. **3**; see FIG. **8**); and (3) a transducer-and-generator ("TAG") assembly **303**. The handle assembly **302** and the ultrasonic-cutting-blade-and-waveguide assembly **304** are pre-coupled but rotationally independent from one another. The battery assembly **301**, according to one exemplary embodiment, is a rechargeable, reusable battery pack with regulated output. In some cases, as is explained below, the battery assembly **301** facilitates user-interface functions. The handle assembly **302** is a disposable unit that has bays or docks for attachment to the battery assembly **301**, the TAG assembly **303**, and the ultrasonic-cutting-blade-and-waveguide assembly **304**. The handle assembly **302** also houses various indicators including, for example, a speaker/buzzer and activation switches.

The TAG assembly **303** is a reusable unit that produces high frequency mechanical motion at a distal output. The TAG assembly **303** is mechanically coupled to the ultrasonic-cutting-blade-and-waveguide assembly **304** and, during operation of the device, produces movement at the distal output of the ultrasonic-cutting-blade-and-waveguide assembly **304**, i.e., the cutting blade. In one embodiment, the TAG assembly **303** also provides a visual user interface, such as, through a red/green/blue (RGB) LED or other display. As such, a visual indicator of the battery status is uniquely not located on the battery and is, therefore, remote from the battery.

The present invention's ability to provide all of the necessary components of an ultrasonic cutting tool in a hand-held package provides a great advantage over prior-art devices, which devices house substantially all of the device components within a very expensive and heavy desktop box **202**, as shown in FIG. **2**, and include an expensive tether **208** between the device's handpiece **112** and the desktop box **202**, which, most significantly, is bulky and interferes with the surgeon's movements. Furthermore, the cord **208** must transit between the sterile field, where the device is present, and the non-sterile area where the generator rests. This sterile-to-non-sterile connection increases the risk of contamination of the sterile field and blurs the boundary between sterile and non-sterile.

In accordance with the present invention, the three components of the handheld ultrasonic surgical cautery assembly **300** are advantageously quickly disconnectable from one or more of the others. Each of the three components of the system is sterile and can be maintained wholly in a sterile field during use. Because each portion can be separated from one or more of the other components, the present invention can be composed of one or more portions that are single-use items (i.e., disposable) and others that are multi-use items (i.e., sterilizable for use in multiple surgical procedures). FIGS. **4** and **5** show the battery assembly **301** and TAG assembly **303** components, respectively, separate from the overall composite assembly shown in FIG. **3**. The details of each of the components are shown and described throughout the remainder of the specification. These details include, inter alia, physical aspects of each component separate and as part of the handheld ultrasonic surgical cautery assembly **300**, electronic functionality and capability of each component separate and as part of the overall assembly **300**, and methods of use, assembly, sterilization, and others of each component separate and as part of the overall assembly **300**. In accordance with an additional embodiment of the present invention, each of the components **301**, **302**/**304**, **303** is substantially equivalent in overall weight; each of these components **301**, **302**/**304**, **303** is balanced so that they weigh substantially the same. The handle **302** overhangs the operator's hand for support, allowing the user's hand to more freely operate the controls of the device without bearing the weight. This overhang is set to be very close to the center of gravity. This, combined with a triangular assembly configuration, makes the overall handheld ultrasonic surgical cautery assembly **300** advantageously provided with a center of balance that provides a very natural and comfortable feel to the user operating the device. That is, when held in the hand of the user, the overall assembly **300** does not have a tendency to tip forward or backward or side-to-side, but remains relatively and dynamically balanced so that the waveguide is held parallel to the ground with very little effort from the user. Of course, the instrument can be placed in non-parallel angles to the ground just as easily.

FIG. **6** provides a general block circuit diagram illustrating the communicative coupling between the battery assembly **301**, the handle assembly **302**, and the TAG assembly **303**. FIG. **6** also shows various power and communication signal paths **601***a-n* between the battery assembly **301** and the handle assembly **302**. The handle assembly **302** provides additional power and communication signal paths **602***a-n* that continue on to the TAG assembly **303**. These power and communication signal paths **601***a-n* facilitate operation, to name a few, of:

1. a buzzer, e.g., audio frequency signal, which provides an audible user interface;
2. a minimum button, e.g., 0 to 3.3 V and 0 to 25 mA input signal, which is a user interface to activate ultrasound output at minimum displacement;
3. a maximum button, e.g., 0 to 3.3 V and 0 to 25 mA, which is a user interface to activate ultrasound output at maximum displacement;
4. a first output voltage (Vout), e.g., 0 to 10 Volt and 0 to 6 A output, from the battery assembly **301** to the TAG assembly **303** and provides power to the TAG assembly **303** to generate a transducer drive signal;

5. a ground or system common connection;
6. a second output voltage (Vbatt), which is a voltage output from battery for providing power for the system;
7. a first communication line (Comm+), which provides differential half duplex serial communications between the battery assembly **301** and the TAG assembly **303**;
8. a second communication line (Comm−), which provides differential half duplex serial communications between the battery assembly **301** and the TAG assembly **303**; and
9. a present line, which, when connected to the handle assembly **302**, activates power in the battery assembly **301** and, thereby, to the entire system.

In accordance with an embodiment of the present invention, the above-described power and communication signal paths **601***a-n* are provided through a flex circuit that spans between a first multi-lead handle terminal assembly on the handle assembly **302** (where the battery assembly **301** electrically couples to the handle assembly **302**) and a second multi-lead handle terminal assembly on the handle assembly **302** (where the TAG assembly **303** electrically couples to the handle assembly **302**). Thus, the flex circuit electrically connects the battery assembly **301** to the TAG assembly **303**.

I. Battery Assembly

FIG. **7** provides a general block circuit diagram illustrating battery assembly **301** and internal components included therein. The battery assembly **301** generally includes one or more battery cells **701**, a battery protection circuit **702**, and a battery controller **703**. Various power and signal paths **704***a-n* run between the battery cells **701** and the battery protection circuit **702**. Power and communication signal paths **706***a-n* run between the battery protection circuit **702** and the battery controller **703**. The power and signal paths **704***a-n* and **706***a-n* can be simple direct connections between components or can include other circuit elements not shown in the figures. The power and communication signal paths **706***a-n* include, among others:

1. a SMBus clock signal (SCLK), which is used for communications between the battery controller **703** and the battery fuel gauge/protection circuit **702**;
2. a SMBus data signal (SDAT), which is used for communications between the battery controller **703** and the battery fuel gauge/protection circuit **702**; and
3. an enable switch that turns off the battery controller **703** when the battery assembly **301** is in a charger by removing power to the switching power supply within the battery controller **703** once grounded.

a. Battery Cells

The battery cells **701** include, in one embodiment, a 4-cell lithium-ion polymer (LiPoly) battery. There is, of course, no limit to the number of cells that can be used and no requirement that the cells be of the LiPoly type. Advantageously, manufacturers can produce LiPoly batteries in almost any shape that is necessary. These types of batteries, however, must be carefully controlled during the charging process, as overcharging LiPoly batteries quickly causes damages to the cells. Therefore, these batteries must be charged carefully. For this reason, the present invention utilizes an inventive battery protection circuit **702**.

b. Battery Protection

The battery protection circuit **702** controls charging and discharging of the battery cells **701** and provides battery protection and "fuel gauge" functions, i.e., battery power monitoring. More particularly, the battery protection circuit **702** provides over-voltage, under-voltage, over-temperature, and over-current monitoring and protection during both the charging and discharging stages. If overcharged, LiPoly batteries cannot only be damaged but can also ignite and/or vent. The battery protection circuit **702** provides multiple levels of protection. For example, the battery protection circuit could provide a triple level of protection for each of current, voltage and temperature. The protection is redundant and uses active components for the first and second levels of protection, and uses passive or redundant components for the higher third level of protection. In one example, the multiple levels of protection provided by the battery protection circuit may utilize components that join the battery cells together, such as PTC devices, thermal fuses, current fuses, and resettable elements.

The "fuel gauge" function of the battery protection circuit **702** limits the discharge of voltage and current, both continuous and transient, on the output of the battery assembly **301**. During charging of the battery cells **701**, the fuel gauge can limit the current level fed to the battery cells **701**. Alternatively, a battery charging unit can perform this current-limiting function. The fuel gauge also monitors temperature and shuts down the battery assembly **301** when a temperature of the battery cells **701** exceeds a given temperature. The fuel gauge is further able to determine how much total energy is left in the battery cells **701**, to determine how much previous charge has been received, to determine an internal impedance of the battery cells **701**, to determine current and voltage being output, and more. By using this data, the present invention, through use of inventive algorithms, is able to determine the "State-of-Charge" (SOC) of the battery cells **701** based in part on the chemical attributes of the battery cells **701** and, in particular, to identify when there is not enough battery capacity to safely perform a surgical procedure as described in further detail below. The system has been programmed to include information regarding how much energy is needed to complete one cutting and cautery procedure safely. With that information stored, the fuel gauge compares that minimum amount of energy needed to the current state of charge of the battery when initially powered to begin a cut/cauterization or at a time during a procedure when a new cut/cauterization is to be performed. If the minimum threshold is not met (e.g., 1000 joules), then the device is not permitted to continue operating.

Furthermore, in order to ensure maximum energy delivery, efficiency and prevent overcharging of individual cells in the battery pack, it is important to verify that the State-of-Charge of all the cells is equal. A good indicator of the SOC is the cell voltage. Thus, during charging, cell voltage is monitored and the amount of current delivered to each cell is adjusted until the voltage of all cells is equalized. At this point, the cells are balanced.

In addition, a thermistor may be installed in the battery pack and located adjacent the battery cells (e.g., either in between two cells, in between all adjacent cells, or next to cells on any side) to provide an external device (e.g., a battery charger) with a measurement or way to monitor the cell temperature within the battery pack.

c. Battery Controller

FIG. **11** is a general block circuit diagram illustrating the internal components of the battery controller **703** of FIG. **7**. As previously shown in FIG. **7**, the battery controller **703** is fed signals and powered through power and communication signal paths **706***a-n*. Additionally, the battery controller **703** also provides output power and signals along power and communication signal paths **601***a-n*. The battery controller **703**, according to one exemplary embodiment of the present invention, includes a power supply **1102**, SMBus isolation switch(es) **1104**, a microcontroller **1106**, an audio driver **1108**, a user buttons interface **1110**, a serial communications transceiver **1112**, and a buck converter **1114**.

The power supply **1102** is composed of two subsystems: a buck switching power supply that first reduces the unregulated cell voltage to a substantially constant direct-current voltage, e.g., 4 VDC. A second linear power supply steps down and regulates the direct-current voltage to a level that is required by the low voltage components used in this device, e.g., 3.3 VDC. This two-step voltage reduction is implemented to ensure low battery consumption. Switching power supplies are inherently efficient, as compared to the traditional linear power supplies, but they tend to produce large output voltage ripple (noise), which could be problematic. Therefore, the voltage is first stepped down using an efficient switching regulator and is then fed to a linear regulator, which produces a better filtered and noise-free voltage to the digital components of the circuit. The output from the switching regulator is also used to feed the audio amplifier, which requires larger voltages and tends to generate additional noise—which is undesirable in the digital section of the circuit.

The SMBus isolation switches **1104** (also referred to as relays) are provided as a way to prevent voltages originating from the operation of the battery protection and charge control circuit, which is ON during the charge process, to be fed into the rest of the battery circuit, which is OFF during the charge process. In an exemplary embodiment, the switches used are optically driven and turned on by the PRESENT circuit in the device (see **601***a-n*).

Microcontroller **1106** is a highly-integrated processing unit that controls the functions of the battery controller **703**. In an exemplary embodiment, the microcontroller **1106** stores and executes the software that allows operation of the device. Given the computational demand imposed by the operation of the device, the microcontroller **1106** is state of the art, for example, including two independent microcontroller cores in one package. In this embodiment, a main core runs a main program, which controls the device. When the device is activated, sampling of the various parameters required to ensure proper and efficient operation are monitored by a second core, for example, the Control Law Accelerator (CLA) **1116**, shown in FIG. **11**. The CLA also can be used to provide proportional-integral-derivative ("PID") control loop operation, which is very computationally demanding. This configuration, therefore, effectively allows one core of the device to run a state machine at very high speeds to maintain full and immediate control of the system while, at the same time, the second core handles the demanding computations of gathering data and handling the control loop. Preferably, the microcontroller **1106** lends itself to low power consumption applications and, therefore, a 3.3 volt unit can be used. Internal oscillators allow device startup without the need of external (and power consuming) components. The microcontroller **1106** can also be configured to have its own internal non-volatile memory section to store program and diagnostic information. The battery microcontroller **1106** monitors input voltage, output voltage, output current, and the battery and buck temperatures to provide total control of the voltage converter functions.

Audio driver **1108** produces a signal that ultimately drives the buzzer **802** that is located in the handle assembly **302**. In an exemplary embodiment, the audio driver **1108** is a simple, but powerful, two-stage class A square wave amplifier. The amplifier is fed directly from the buck switching power supply (e.g., 4 VDC) to ensure maximum power capability. The amplifier is able to drive an audio speaker (no internal driver). Feeding the audio driver **1108** from the buck switching power supply also insures that noise generated by the audio amplifier is not fed to the supply rail of the digital and analog components of the device, which ensures noise-free operation. Capability to regulate volume by changing a single resistor is provided in case adjustment is necessary.

The user buttons interface **1110** conditions the signals received from the minimum **804** and maximum **806** activation switches housed within the handle assembly **302**. In an exemplary embodiment, the user buttons interface **1110** is operable to continuously measure impedance of the activation switches to prevent false activation, for example, in the case of fluid ingress at the button. The battery controller **703** measures the impedance of the switch(es) and will not activate the system until the impedance detected falls below a predetermined threshold. This configuration eliminates accidental activations due to fluid ingress, which are generally detected as higher impedances in the switch(es) than that of a fully closed switch. The PRESENT line works on a similar principle, ensuring that the PRESENT line is closed through a low enough impedance before the battery is turned on. This is done so that exposure of the PRESENT pin to any conducting fluid will not accidentally turn on the battery pack. The user buttons interface **1110** operates in this exemplary embodiment by injecting a known current level through the switch lines. When the button is open (no activation) the current source will maximize its voltage output and this voltage is measured by the microcontroller **1106**. When the switch is closed, the current source will adjust its voltage output to generate its target programmed current. If the button is working at optimally low impedance, the voltage output will be low. However, in the case where fluid enters the button, the impedance seen by the current source will be high, and a proportionally equivalent voltage, higher than that generated for a closed button, will indicate to the microcontroller **1106** that activation should not occur.

The exemplary embodiment of the circuitry is equipped with a calibrated current source, which can be used to calibrate the programmable current source during startup and to provide a tighter detection window. This calibration that occurs during the device startup narrows the window or impedance range in which a positive activation is detected. The calibration is performed by switching the circuitry of the impedance circuit to a precision current source and measuring the voltage to calibrate the circuit. During the device startup procedure, the battery controller can self-calibrate the activation button impedance detection circuitry to reduce the impedance range required to discern between a true button closure (activation) and an inadvertent activation signal that is erroneously caused by fluid contamination of the button(s).

Activation button impedance is measured by flowing a pre-determined current level through the button lines using a current source. By measuring the voltage across the contacts, Ohm's Law (i.e. R=V/I) can be used to determine the resistance in the line. During calibration, two analog switches are used. The first switch connects the microcontroller serial communication lines to the programmable current source to be able to control the current source. The second switch connects the output of the current source to a set of precision resistors. The current flow is adjusted by the microcontroller until a given voltage measurement (i.e. calibration value) is achieved. Once adjusted, the first switch is changed to connect the microcontroller to the SMBus lines and the second switch connects the current source to the activation button(s) to resume normal operation.

The microcontroller can switch the SMBus lines to be connected to the analog switch or to the main SMBus line. This allows the switch (non SMBus) to function and, at the same time, allows the microprocessor to connect to the SMBus lines.

In an exemplary embodiment, the serial communications transceiver **1112** allows the battery **301** to establish communication with the TAG **303** and external devices that can be used to obtain diagnostic or calibration information from the device. The serial communications transceiver **1112** provides transmission and reception of differential half-duplex communications between the battery controller **703** and the generator **904**. The transceiver **1112** is capable of detecting loss of hardware connection for fault detection in addition to the explained software fault detection. An exemplary embodiment of the device used is configured to be compatible with USB communications for reliability and it can be used in a differential mode for common-mode noise rejection. Given the amount of data that the battery **301** exchanges with the TAG **303**, a full-speed device is used (e.g., up to 12 Mbit/s).

Many possible fault conditions can be detected and responded to by the system, the responses sometimes taking the form of feedback to the user. For example, the system can issue a fault condition when a stuck switch condition exists. Such a condition can include when the high/low activation switch is improperly in the activated position at system start up, or where the high activation switch is activated but the low activation switch has not been activated, or where the high/low activation switch is in the activated position at the end of a use cycle. Other fault conditions exist when there is insufficient motional feedback or when the waveguide tip is in a stalled condition. Both low amplitude displacement and high amplitude displacement can cause a shutdown if detected. Various faults are associated with the TAG. For example, a fault condition exists where the output voltage is greater than a defined voltage limit. Another fault condition exists when the microprocessor temperature is greater than a given predefined range, for example, greater than approximately 100 degrees Celsius. Another fault occurs when the battery controller does not receive proper acknowledgement from the TAG either before, during ultrasonic start, or after ultrasonic start. Some fault conditions are associated with the battery. For example, if the battery charge is below any number of predefined thresholds or if a load requires more power than the system can deliver and the amplitude drops below the desired threshold, faults can be indicated. Other faults of the battery can include a failure of the battery's communications system, an over-temperature condition of the battery's microprocessor, fuel gauge, and/or regulator. Failure of the communications system can be through either or both of the TAG and battery. General faults of the system can be included as well. If the CLA ceases to function or functions inappropriately, a fault can be indicated. Failure to reset timers associated with the battery and the TAG can also indicate faults. Software failures also can trigger faults.

Lastly, in the exemplary embodiment, the buck converter **1114** provides step down voltage control to provide amplitude regulation. The buck converter **1114** steps down the battery voltage to produce a lower voltage for delivery to the TAG assembly **303** for generation of the ultrasound output signal to the transducer **902**. The microcontroller **1106** controls the output of the buck regulator by varying or modulating the pulse widths of the input signals to the buck converter (i.e., pulse width modulation (PWM)). Off-phase PWM inputs are used for minimal output ripple. The device operates at 300 KHz for high efficiency using small inductors and capacitors. The buck converter **1114** is of a multi-phase synchronous design for maximum possible efficiency. The design utilizes high integrated components for small size and power consumption. The device includes internal current protection, output current sensing, output and input voltage sensing and over-temperature protection. The buck converter **1114** is capable of reacting at high speeds and step down voltages in the range of 2 VDC to 10.5 VDC.

The power supply **1102** produces various voltage levels at its output, which are used to power the various battery controller components shown in FIG. **11**. The SMBus isolation switch(es) **1104** is/are used to disconnect the SMBus lines to the battery protection printed circuit board during charging and when the bus is used for other purposes within the battery controller.

As set forth in detail below, the battery controller **703** facilitates a user interface, e.g., a buzzer **802** and RGB LEDs **906**, and converts the output voltage and current output of the buck converter **1114**, which output powers the TAG assembly **303** through at least one voltage output path (V_{out}) **601***a-n*.

II. Handle Assembly

FIG. **8** is a general block and schematic circuit diagram illustrating the handle assembly **302** shown in FIG. **3**. The handle assembly **302** receives control and power signals over attached power and communication signal paths **601***a-n*. A second set of power and communication signal paths **602***a-n* connect to the TAG assembly **303** when it is attached to the handheld ultrasonic surgical cautery assembly **300**. As is explained in detail below, the handle assembly **302** houses the ultrasonic waveguide assembly **304** and provides a portion of the pistol grip that the operator uses to grasp and operate the entire handheld ultrasonic surgical cautery assembly **300** using, for example, a two-stage switch of button **4608** and trigger **4606** (as introduced in FIG. **46**). The handle assembly **302**, according to one exemplary embodiment, is provided with a speaker/buzzer **802** capable of receiving a buzzer output signal from the battery assembly **301** through a signal path **601***a-n* and of producing an audible output, e.g., 65 db, suitable for communicating specific device conditions to an operator. These conditions include, for example, successful coupling of assembly components (e.g., battery assembly **301** to handle assembly **302**), high, low, or normal operation mode, fault conditions, low battery, device overload, mechanical failure, electrical failure, and others. The handle also includes a Min. Button switch **804** and a Max. Button switch **806** that, when activated, connects the respective button to ground (for example), which in an exemplary embodiment signals the battery controller to start the ultrasonic output in either low or high displacement mode. The handle assembly **302** also provides a pass-through interconnect for signals between the battery assembly **301** and the TAG assembly **303**.

The speaker/buzzer **802** and the Min. and Max Button switches **804**, **806** are all part of the flex circuit of the handle assembly **302**. According to an exemplary embodiment of the present invention, the buzzer **802** is held in place within the handle assembly **302** with the use of an extra tab of flex material that protrudes outward past the edge of the buzzer **802**. This tab **10802** can be seen in FIGS. **108** and **110**. The handle assembly **302** includes a slot **11002** configured to receive the flexible tab **10802** of material during assembly. The buzzer **802** is protected from fluid ingress by a buzzer seal, for example, an acoustically transparent mesh with adhesive on both sides that bonds the buzzer into the handle assembly **802** while still allowing sound to exit and prevent fluid from entering into the buzzer **802**.

III. TAG

FIG. **9** is a block and schematic circuit diagram illustrating the TAG assembly **303** of FIGS. **3** and **5**, which houses the transducer **902** and the generator **904**. The generator **904** converts DC power from the battery controller **703** into a higher-voltage AC signal that drives the transducer **902**, which converts the electrical signal into mechanical motion.

a. Generator

FIG. **10** is a block circuit diagram illustrating the internal components of the generator **904**. The generator **904**, according to an exemplary embodiment of the present invention, includes a power supply **1002**, a serial communications transceiver **1004**, a microcontroller **1006**, a numerically controlled oscillator ("NCO") **1008**, a push/pull switching amplifier **1010**, an output filter/matching network **1012**, a motional bridge **1014**, a feedback amplifier and buffer(s) **1016**, an LED driver **1018**, and indicators **906** (for example, RGB LEDs). The power supply **1002** receives power from the battery assembly **301** through lines Vbatt and GND of the power signal paths **602***a-n* and outputs various voltages that are used to power the generator **904**. The serial communications transceiver **1004** provides transmission and reception communications between the battery controller **703** and the generator **904**, here, through a serial data link Comm+/Comm− of the communication signal paths **602***a-n*, although this communication can occur through a single line or through a number of lines, in series or in parallel.

The microcontroller **1006** is a highly integrated processing unit that controls the functions of the generator **904** and is one of two microcontrollers in the system, the other being part of the battery controller **703**. In the exemplary embodiment, a serial data link (Comm+, Comm−) exists between the two microcontrollers **1006**, **1106** so they can communicate and coordinate their operation. The microcontroller **1006** in the TAG **303** controls generation of the high-voltage waveform driving the piezoelectric transducer **902**. The microcontroller **1106** in the battery assembly **301** controls conversion of the DC voltage from the battery cells **701** to a lower DC voltage used by the TAG **303** when generating the high voltage AC to the transducer **902**. The battery microcontroller **1106** regulates the DC output of the battery assembly **301** to control the amplitude of the mechanical motion, and the TAG microcontroller **1006** controls the frequency of the signal that drives the transducer **902**. The battery microcontroller **1106** also handles the user interface, and the battery protection circuit **702** monitors the battery cells **701** during system operation. The microcontroller **1006** in the TAG **303** has a variable speed system clock that is adjusted constantly while the device is running in the high-power state in order to keep the microcontroller **1006** synchronized with the ultrasonic motion. The microcontroller **1106** in the battery assembly **301** runs at a fixed frequency while in the high-power state, regardless of the TAG clock. Because the system clock varies in frequency, a scale factor within the TAG microcontroller **1006** is changed along with the changing system clock to keep serial communication between the microcontrollers **1006**, **1106** within the range of proper operation.

Direct digital synthesis ("DDS") is a technique used to generate a periodic waveform with a precise output frequency that can be changed digitally using a fixed frequency source. The numerically controlled oscillator ("NCO") **1008** is a signal source that uses the DDS technique, which can be performed through hardware or software. The fixed frequency input to the DDS is used to generate a clock for the NCO **1008**. The output is a series of values that produce a time-varying periodic waveform. A new output value is generated during each clock cycle.

The DDS **2200**, which is shown in schematic detail in FIG. **22**, works by calculating the phase component of the output waveform that is then converted to amplitude, with a new phase value being generated each clock cycle. The phase value is stored in a variable register **2202**, which register is referred to herein as the "phase accumulator." During each clock cycle, a fixed number is added to the number stored in the phase accumulator to produce a new phase value. This fixed number is often referred to as the frequency control word or frequency tuning word because it, along with the clock frequency, determines the output frequency. The value in the phase accumulator spans one cycle of the periodic output waveform from 0 to 360 degrees, with the value rolling over at 360 degrees.

The value in the phase accumulator is fed into a phase-to-amplitude converter **2204**. For a sine wave, the amplitude can be computed using the arctangent of the phase value. For high speed applications, the converter usually uses a lookup table to generate the amplitude value from the phase value.

In a hardware implementation of DDS, the output of the amplitude converter is input to a digital-to-analog converter (DAC) **2206** to generate an analog output signal f_{out}. The analog signal is usually filtered by a band pass or low pass filter to reduce unwanted frequency components in the output waveform.

As a first example, the value in the phase accumulator **2202** can be set to an integer from 0 to 359. If the frequency tuning word is 1, the value in the phase accumulator **2202** will be incremented by 1 each clock cycle. When the value reaches 359, it rolls over to zero. If the clock frequency is 360 Hz, the frequency of the output waveform will be 1 Hz. The output will, therefore, be a series of 360 points during each 1 second period of the output waveform. If the frequency tuning word is changed to 10, the value in the phase accumulator is incremented by 10 each clock cycle, and the output frequency will be 10 Hz. The output will therefore be 36 points for each period of the output waveform. If the frequency tuning word is 100, the output frequency will be 100 Hz. In that case, there will be 3.6 points for each output period. Or, more accurately, some cycles of the output waveform will have 3 points and some will have 4 points, the ratio of cycles with 4 points versus 3 points being 0.6.

As a second example, the value in the phase accumulator **2202** can be a 10 bit number. The 10 bit number will have 1024 possible values. With a frequency tuning word of 50 and a clock frequency of 1 MHz, the output frequency will be 50*1 MHz/1024=48.828 kHz. FIG. **23** illustrates the output **2300** of the DAC **2206** and what the filtered DAC output might look like.

If the frequency tuning word is 22, the output frequency is 22*1 MHz/1024=21.484 kHz. In this case, FIG. **24** illustrates the output **2400** of the DAC **2206** and what the filtered DAC output might look like. When power is first applied to the generator, the state of the NCO **1008** may be undefined (or the output of the NCO **1008** may not be at a suitable frequency). This could lead to improper operation of the microcontroller. To ensure proper operation of the microcontroller, the NCO **1008** is not used to drive the clock frequency of the microcontroller when power is first applied. A separate oscillator is used. In one exemplary embodiment, the separate oscillator is integrated into the microcontroller **1006**. Using this separate oscillator, the microcontroller initializes the various memory locations internal to the microcontroller and those in the NCO **1008**. Once the NCO **1008** is operating at a suitable frequency, the microcontroller switches the source of its clock from the separate oscillator to the NCO **1008**.

If the frequency tuning word is 400, the output frequency is 400*1 MHz/1024=390.625 kHz. In this case, FIG. **25** illustrates the output **2500** of the DAC **2206** and what the filtered DAC output might look like. The output sometimes has 2 points per period and sometimes 3 points. The waveform in FIG. **25** clearly shows the need for a filter to obtain a clean sine wave.

Referring back to FIG. **10**, the push/pull switching amplifier **1010** converts DC power from the battery controller **703** into a higher voltage square wave. The output filter/matching network is a passive filter that changes the square wave from switching amplifier **1010** into a smooth sinusoidal wave suitable for feeding to the transducer **902**. The motional bridge **1014** is a circuit that produces a feedback signal in proportion to and in phase with the mechanical motion of the transducer **902** and waveguide assembly **304**. The feedback amplifier and buffer(s) **1016** amplifies and buffers the motional feedback signal determined within the motional bridge **1014**. As will be explained in greater detail below, the motional bridge **1014** allows the device to run with a constant displacement/amplitude mode and varies the voltage as the load varies. The motional bridge is used to provide amplitude feedback and, by virtue of using this type of feedback, i.e., motional feedback, the system is able to run with constant current.

In one embodiment, the TAG assembly **303** includes one or more red/green/blue (RGB) LEDs **906**, which can be used for a variety of warning and communication purposes. For example, green can indicate the device is functioning normally whereas red indicates the device is not functioning normally. It is noted that the placement of the LEDs **906** at the generator **904** in FIG. **9** is only for illustrative purposes. The invention envisions placing the indicators anywhere at the TAG assembly **303**.

Through communicative interaction between the handle assembly **302** and the TAG assembly **303**, in particular, the speaker **802** and the LEDs **906**, the inventive handheld ultrasonic surgical cautery assembly **300** provides full feedback to an operator during use to indicate a plurality of conditions associated with the ultrasonic surgical cautery assembly **300**, whereby the feedback originates from the handle and not remotely. For instance, as mentioned above, the speaker/buzzer **802** can provide audible warnings and audible indicators of operational status of the ultrasonic surgical cautery assembly **300**. A full class A or B amplifier (e.g., a full amplifier or an ON/OFF square-pulse amplifier) could be used to provide a broader frequency range to implement different sounds and/or audible messages. Similarly, the LEDs **906** can provide visual warnings and visual indicators of the operational status of the ultrasonic surgical cautery assembly **300**. As an example, the LEDs **906** can provide an indication of an amount of power remaining within the battery cell(s) **701** or a lack of sufficient power to safely carry out a surgical procedure. For instance, a first color of the LEDs **906** indicates a fully charged battery cell(s) **701**, while a second color indicates a partially charged battery cell(s) **701**. Alternatively, various blinking patterns or constant on states of the LEDs **906** can provide condition indicators to the user. The LED driver **1018** that is shown in FIG. **10** is an exemplary configuration that provides a constant current when the LEDs **906** are illuminated. Importantly, all of the feedback indicators to the user are uniquely present on the handheld device and do not require the user to be within range of a remote feedback component that is away from the surgical field of vision or outside of the sterile field. This eliminates the requirement for the physician to shift his/her attention from the surgical field to a remote location to verify the nature of the feedback signal.

However, should it prove useful to relay or transmit any of the feedback indications to a device that is external to the handheld device, circuitry can be implemented in the generator or battery board(s) to provide a radio-frequency link (or other forms of communications links) for downloading, transferring or transmitting user interface, diagnostics, or other relevant data from the handheld device to the external device. In this way, the external device allows for the surgical staff or others overseeing the procedure, but who are not inside the surgical field or within the immediate vicinity of the handheld device, to receive the same relevant indications or pieces of information that are being received by the physician. The external device may also function as a valuable backup source or data log for storing information pertaining to the use and diagnostics of the handheld device. The external device may also be utilized to provide a range of more powerful data processing or software applications or tools than can reasonably be implemented in the handheld device. For example, the external device may be able to provide analytical or diagnostic results from the information being received from the handheld device. The handheld device and the external device may also be equipped with bi-directional communication such that the external device could re-program the internal software of the handheld device or issue commands or controls to the handheld device in an advantageous manner.

b. Transducer

A transducer **902** is an electro-mechanical device that converts electrical signals to physical movement. In a broader sense, a transducer **902** is sometimes defined as any device that converts a signal from one form to another. An analogous transducer device is an audio speaker, which converts electrical voltage variations representing music or speech to mechanical cone vibration. The speaker cone, in turn, vibrates air molecules to create acoustical energy. In the present invention, a driving wave **1400** (described below) is input to the transducer **902**, which then converts that electrical input to a physical output that imparts movement to the waveguide **1502** (also described below). As will be shown with regard to FIG. **15**, this movement sets up a standing wave on the waveguide **1502**, resulting in motion at the end of the waveguide **1502**. For purposes of the present invention, transducer **902** is a piezo-electric device that converts electrical energy into mechanical motion.

As is known, crystals in piezoelectric transducers expand when voltage is applied. In a transducer configuration according to the invention, as illustrated for example in FIG. **55**, the crystals are clamped into a crystal stack **5502**. See also FIGS. **54** and **56** to **58**. A clamp bolt **5504** in this configuration acts as a spring if it is set to pre-compress the crystal stack **5502**. As such, when the crystal stack **5502** is caused to expand by imparting a voltage across the stack **5502**, the clamp bolt **5504** forces the stack **5502** back to its original, pre-compressed position (i.e., it retracts). Alternatively, the clamp bolt **5504** can be torqued so that there is no pre-compression on the stack **5502** and, in such a case, the bolt will still act as a spring to pull the mass back towards it original position. Exemplary configurations of the transducer can be a so-called Langevin transducer, a bolt-clamp Langevin transducer, or a bolt-clamped sandwich-type transducer.

When an ultrasonic transducer is caused to vibrate, a standing wave is established at the distal portion of the transducer. This standing wave extending along the transducer **902** and the waveguide **1502**, exhibits nodes (points of minimal vibration) and anti-nodes (points of maximum vibration). Placement of the nodes and anti-nodes is important. For example, the blade portion **7304** is positioned at an anti-node because greatest vibratory characteristics are desired there. The same is true for the distal-most end, the ultrasonic waveguide couple **5004** of the transducer **902** as the greatest vibratory characteristics are desired to be coupled into the waveguide **1502**. In the exemplary embodiment of the transducer illustrated in FIGS. **54** to **58**, the node (the point at which vibration movement is lowest) exists where it is secured to the TAG assembly **303**. This is beneficial because imparting vibration onto/into the TAG assembly **303** is not desirable.

In the transducer **902**, a step-down in diameter is referred to as a gain-step because downstream vibratory characteristics increase as the circumferential diameter decreases. In the cross-sectional view of FIG. **54**, for example, two gain-steps can be seen between the crystal stack **5502** and the ultrasonic waveguide couple **5004**. Also present in this view is the flange **5450** of the transducer **902**, which is the contact point of the transducer **902** to its housing. This contact point **5450** is located at a node of the transducer **902**.

In an alternative exemplary embodiment to the transducer, **902**, the crystal stack **5502** can be displaced and, in doing so, provides a more efficient system. More specifically, by moving the crystal stack **5502** more proximally, the gain step that is adjacent to the crystal stack **5502** is moved closer to the node, thereby increasing the overall gain of the system. The required displacement of the crystals is less with greater gain. The further the crystal is away from the node the less it contributes to the power handling capability. Therefore, it is desirous to have the node within the crystal stack but also as close to the gain step as possible. When more than one crystal is placed on one side of the node they work in series, thereby increasing the total displacement. As the crystals move further from the node, their contribution to the displacement is decreased because of their distance from the node. When crystals are placed on both sides of the node, they work in parallel to increase the power capacity of the system but do not increase the overall displacement. This configuration, therefore, reduces how hard the crystals need to be driven to get the same output. As losses go with the square of how hard the crystal are driven (current), lower current means it is more efficient. An amplitude versus power curve shows a typical squared relationship. From this, it can be seen that, in a space-limited system such as the TAG, such a configuration generates the most gain out of the system. In high drive conditions, there is an increased sensitivity to the losses in the crystals. But, by having the increased gain described here, the crystals do not have to be driven so close to the maximum power and, thereby, avoids this sensitivity. It is known that higher power through dielectric losses generates heat. Such heat leads to depolling and causes a frequency shift, which can result in a change in capacitance that move the nodes away from the normal supporting point(s), causing the output to decrease and to generate unwanted heat at other unforeseen places, which can further exacerbate this problem. Furthermore, with appropriate wiring, it is possible to selectively drive only a portion of the crystal stack, which increases efficiency when the load is low.

The transducer **902** of the invention is housed in a cylindrical casing **5430** that has an opening at the distal end to allow the horn **5002** to protrude. The transducer **902** also has two conductive rings **5406**, **5408** that surround the transducer and carry the electrical signal from the generator **904** to the transducer **902**. In an exemplary embodiment, the rings **5406**, **5408** are single machined parts that are made as a flat part either by stamping or machining that, then, has a leg bent into the correct form. Alternatively, the leg can be a second part that is pressed or soldered into a flat ring. These ring/leg sets are overmolded to a distal housing portion **5434** of the transducer housing. The overmolding is not sufficient to create a gas-tight seal. Accordingly, a well is molded where the leg of the ring exits the plastic, which well can be filled with a potting material that creates the gas-tight seal. Alternatively, the leg can be a round pin. In such a case, an o-ring can be placed between the leg and the well to create the seal. The electrodes **5802**, **5804** of the transducer crystal stack **5502** can be formed to have spade or pin style connector shapes that allow the electrical connection of the transducer to the leg to happen without solder. This simplifies manufacture and eliminates exposing the leg to heat from soldering, which could further compromise the seal. Portions of the connectors are illustrated in FIGS. **54** to **58** but are best seen in FIG. **58**. The transducer **902** needs to be held by the flange **5450**, which is at a node where no vibration occurs. The transducer **902** also needs to be rotationally locked to its housing, which can be accomplished with standard key-like features shown, for example, in FIG. **55**, or can be done with four flats. By using flats, the wall thickness of the housing can be increased in the area of the contact rings, which increases the structure of this housing that will be exposed to repeated sterilization cycles. To create a seal between the transducer horn **5002** and the housing **5430**, in an exemplary embodiment, the support flange is compressed against an o-ring **5452**, which is supported by the distal housing portion **5434**. To compress this seal sufficiently, the flange **5450** of the transducer **902** must be forcibly pushed against the o-ring **5452**. To push on the interior face of the flange **5450**, a pair of hermaphroditic pushers **5454** extend into the distal housing portion **5434** to allow the completion of the assembly to apply forward pressure through an elastomeric grommet. In an exemplary configuration, a pair of pusher parts is used to fit within a smaller diameter section of the horn because a single part would have to have clearance over the crystals and electrodes and, therefore, would force the overall housing diameter to be much larger. These pushers can also have crush pin features to join them together to facilitate easier installation. The pushers have geometries that lock them rotationally into the keying features of the housing. Further keying features on the proximal end of the pushers can key the proximal housing portion **5432** onto the assembly of the transducer **902** to align clearances within the proximal housing portion **5432** with the electrodes **5402**, **5404** of the transducer **902**. Mating of the proximal housing portion **5432** to the distal housing portion **5434** either with adhesive or welding or other bonding measures is done with sufficient pressure to drive the pushers forward into the grommet, which, in turn, pushes on the flange **5450** and compresses the o-ring **5452** between the flange **5450** and the distal housing portion **5434** to simultaneously create a seal and support the flange **5450** with elastomers on both sides, thereby reducing acoustical coupling between the transducer **902** and the housing **5430**. Alternatively the proximal and distal housing portions **5432**, **5434** can be joined with threads, the tightening of the threads creating compression of the above-described stack of parts. Alternative embodiments can accomplish the same result without the need to insert mold the contact rings by having other elastomeric seals between the rings **5406**, **5408** and the housing **5434**.

As described in further detail below, the transducer **902** is held in the TAG assembly **303** housing with a spiral ring or other retaining clip **5442** that is installed in a groove in a distal most portion of the distal housing portion **5434**. Between the distal housing portion **5434** of the transducer **902**, and the lower housing portion **5030** of the generator **904** is a ring of lubricious material, such as PTFE, that reduces rotational friction. Reduction of friction is important in this area because it is this force-bearing surface that holds the TAG assembly **303** into the handle **302** and compresses the seal around the electrical connection between the TAG assembly **303** and the handle **302**.

IV. Signal Path

FIG. **12** is a block diagram illustrating the signal path between the battery assembly **301** and the TAG assembly **303**. As described further below, the design characteristics of the signal path and the interconnecting circuit components are determined, in part, by the acute objective to protect the signal integrity and efficiency of the components at this critical, and highly vulnerable, juncture between the power source and signal-generating circuitry.

First, a DC-DC step-down converter **1202** steps the voltage from the battery cells **701** down from a first voltage to a second, lower voltage. The DC-DC step-down converter **1202** includes the multi- or variable-phase (depending on the amount of power needed) buck converter **1114** and the battery microcontroller **1106**, which are both shown in FIG. **11** within the battery assembly **301**. The battery microcontroller **1106** controls the buck converter **1114** to regulate the DC voltage fed to the TAG assembly **303**. Together, the buck converter **1114** and the microcontroller **1106** perform the DC-to-DC conversion function in the battery assembly **301**. In an exemplary embodiment of the invention, a two-phase buck converter **1114** is used. Another exemplary embodiment can utilize a buck converter having additional phases. In such a case, phase shedding can be employed. The number of phases used can change dynamically to keep the converter operating at optimal efficiency, which is a consideration for a battery powered device. In other words, when less output power is required, the power losses internal to the converter can be reduced by reducing the number of active phases.

Uniquely, the generator printed circuit board is double-sided, in that the circuitry components are found on both sides of the board. In the exemplary embodiment, the power circuit components are installed on the top side of the PCB, the digital components are installed on the bottom of the board. A solid ground plane separates the two sides. Advantageously, by isolating the high-voltage power circuitry from the logic circuitry in this manner, the logic circuitry is effectively shielded from the injurious high-voltage noise that may be present in the power circuit.

The DC output voltage from the battery assembly **301** powers the push/pull switching amplifier **1010** in the TAG assembly **303**, which assembly **303** converts the DC signal to a higher voltage AC signal. The TAG microcontroller **1006** controls the amplifier **1010**. The output voltage of the push pull switching amplifier **1010** is, in general, a square wave, an example of which is shown in FIG. **13**, which waveform **1300** is undesirable because it is injurious to certain components, in particular, to the transducer **902**. Specifically, the abrupt rising and falling edges of a square wave cause corresponding abrupt starts and stops of the ultrasonic waveguide to produce a damaging "rattling" affect on the waveguide. The square wave **1300** also generates interference between components. For example, higher additional harmonic frequencies of a square wave can create unwanted electrical interference and undesired operation of the circuit(s). This is in contrast to a pure sine wave, which only has one frequency.

To eliminate the square wave, a wave shaping or matching circuit **1012** (sometimes referred to as a "tank circuit") is introduced. The tank circuit **1012** includes such components as, for example, an inductor, along with a capacitor in conjunction with the transducer capacitance, and filters the square wave into a smooth sine wave, which is used to drive the transducer **902** in a way that produces non-damaging ultrasonic motion at the waveguide. An exemplary sine wave **1400** suitable for driving the transducer **902** is shown in FIG. **14**. The matching circuit **1012**, in one exemplary embodiment of the present invention, is a series L-C circuit and is controlled by the well-known principles of Kirchhoff's circuit laws. However, any matching circuit can be used to produce a smooth sine wave **1400** suitable for driving the transducer **902**. In addition, other driving signals can be output from the matching circuit **1012** that are not smooth sine waves but are useful for driving the transducer **902** in a way that is less injurious than a square wave.

Importantly, the design of the power filtering circuit is such that small variations in the inductance of the power inductor will not cause the system to operate outside its specifications. This configuration reduces sensitivity to variations in tuning of the LC filter and, thereby, eliminates the need to incorporate an adjusting screw.

In practice, the matching network **1012** is tuned to match a particular transducer to which it feeds. Therefore, transducers and matching networks are best matched if they remain as a pair and are not placed in combination with another device. In addition, if each transducer **902** had its own matching network, the smart battery **301** could feed different frequencies to the different transducers, the frequencies being respectively matched to a particular blade in a waveguide assembly **304**. Two popular frequencies for ultrasonic surgery devices are 55 kHz and 40 kHz.

In addition, to prevent radio-frequency or electro-magnetic interference from entering the generator circuitry from the ultrasonic waveguide and transducer components, ferrite beads (or, coils) are installed in the generator output lines or traces to block the interference from reaching the circuitry.

Furthermore, the output traces of the generator are configured to be close to one another (e.g., in a triangular double trace) and in parallel to act as a common mode for filtering out any interference (i.e., to allow maximum common mode rejection).

V. Resonance

FIG. **15** is a diagrammatic illustration of the affect that a resonant sine wave input to the transducer **902** has on the waveguide **1502** of the ultrasonic cutting device. In accordance with an exemplary embodiment of the present invention, the sinusoidal pattern shown by the dotted lines in FIG. **15** represents the amplitude of axial motion along the length of the waveguide **1502**, which is coupled to the transducer **902**. Responding to a rising portion **1402** of the driving sine wave **1400** (shown in FIG. **14**), the stack expands in a first direction **1508**. During the negative portion **1404** of the driving wave **1400** (shown in FIG. **14**), the pre-compression or the induced compression of the stack returns the stack to its steady-state, i.e., the portion **1504** of the transducer **902** is moved in a second direction **1512**. As stated above, a smooth sine wave **1400**, in contrast to the square wave **1300**, allows the transducer **902** and waveguide **1502** to slow before changing directions. The smoother movement is less injurious to the device's components.

The alternating movement **1508**, **1512** of the transducer portion **1504** places a sinusoidal wave **1514** along the length of the waveguide **1502**. The wave **1514** alternatingly pulls the distal end **1520** of the waveguide **1502** toward the transducer **902** and pushes it away from the transducer **902**, thereby longitudinally moving the distal end **1520** of the waveguide **1502** along a distance **1518**. The tip of the waveguide **1502** is considered an "anti-node," as it is a moving point of the sine wave **1514**. The resulting movement of the waveguide **1502** produces a "sawing" movement along distance **1518** at the distal end **1520** of the waveguide **1502**. (The wave **1514** and linear movement along distance **1518** are greatly exaggerated in FIG. **15** for ease of discussion.) This high-speed movement along distance **1518**, as is known in the art, provides a cutting instrument that is able to easily slice through many materials, in particular, tissue and bone. The rapidly moving distal end **1520** of the waveguide **1502** also generates a great deal of frictional heat when so stimulated, which heat is absorbed by the tissue that the waveguide **1502** is cutting. This heat is sufficient to cause rapid cauterization of the blood vessels within the tissue being cut.

If the driving wave **1514** traveling along the waveguide **1502** is not a resonant wave, there will be no standing wave, which means that are no nodes or antinodes. This means that there is very little motion. There also exists the possibility of operating the device at an incorrect resonant frequency. Operating at the wrong resonance can produce, for example, undesirable motion such as "slapping." In such a case, the distal end **1520** of the waveguide **1502** moves transverse to the longitudinal axis of the waveguide **1502**. Any incorrect mode is not ideal and is unreliable for providing adequate cutting and surgical cautery. The invention, however, as is explained below, utilizes a phase locked loop (PLL) in the generator **904** to ensure that the movement **1508**, **1512** of the waveguide **1502** remains resonant along the waveguide **1502** by monitoring the phase between the motional current and motional voltage waveforms fed to the transducer **902** and sending a correction signal back to the generator **904**. The TAG microcontroller **1006** controls the frequency and ensures it is in the proper range so as not to excite an undesired resonant frequency. As an added feature, the present invention can be provided with piezo-electric crystal stacks **1504** that are cut in varying planes, thereby creating a torsional, or twisting motion of the blade rather than only a sawing motion. The present invention can easily be adapted to a full set of uses using requiring a drilling-type motion instead of or with the sawing motion just described.

As just explained, ideally, the transducer **902** and waveguide **1502** are driven at their resonant frequency. Resonance is achieved when current and voltage are substantially in phase at the input of the transducer **902**. For this reason, the generator **904** uses the PLL and the signals derived from the current and voltage input to the transducer **902** to synchronize the current and voltage with one another. However, instead of simply matching the phase of the input current to the phase of the input voltage, the present invention matches the current phase with a phase of the "motional" voltage and/or matches the input voltage phase with a phase of the "motional" current. To accomplish this, a motional bridge circuit is used to measure the mechanical motion of the transducer and waveguide and to provide feedback as to the operation of the transducer and waveguide. The motional feedback signal from the bridge is proportional to and in phase with the motion of the transducer **902** and waveguide **1502**.

VI. Motional Control

a. Transducer Circuit Model

FIG. **16** is a schematic circuit diagram of a model transducer **1600**, such as transducer **902**, which contains piezo-electric material. Piezo-electric transducers are well known in the art. The mass and stiffness of the piezo-electric material creates a mechanically resonant structure within the transducer. Due to the piezo-electric effect, these mechanical properties manifest themselves as electrically equivalent properties. In other words, the electrical resonant frequency seen at the electrical terminals is equal to the mechanical resonant frequency. As shown in FIG. **16**, the mechanical mass, stiffness, and damping of the transducer **902** may be represented by a series configuration of an inductor/coil L, a capacitor C_2, and a resistor R, all in parallel with another capacitor C_1. The electrical equivalent transducer model **1700** is quite similar to the well-known model for a crystal.

Flowing into an input **1610** of the electrical equivalent transducer model **1600** is a transducer current i_T. A portion i_C of i_T flows across the parallel capacitor C_1, which is of a type and value that, for the majority of the expected frequency range, retains a substantially static capacitive value. The remainder of i_T, which is defined as i_M, is simply i_T-i_C and is the actual working current. This remainder current i_M is referred to herein as the "motional" current. That is, the motional current is that current actually performing the work to move the waveguide **1502**.

Known prior-art designs regulate and synchronize with the total current i_T, which includes i_C and is not an indicator of the amount of current actually causing the motion of the waveguide **1502** by the transducer **902**. For instance, when the blade of a prior-art device moves from soft tissue to denser material, such as other tissue or bone, the resistance R increases greatly. This increase in resistance R causes less current i_M to flow through the series configuration R-L-C_2, and more current i_C to flow across capacitive element C_1. In such a case, the waveguide **1502** slows down, degrading its performance. It may be understood by those skilled in the art that regulating the overall current is not an effective way to maintain a constant waveguide displacement. As such, one novel embodiment of the present invention advantageously monitors and regulates the motional current i_M flowing through the transducer **902**. By regulating the motional current i_M, the movement distance of the waveguide **1502** can be regulated easily.

b. Series Circuit Model

FIG. **17** is a schematic circuit diagram of an inventive circuit **1700** useful for understanding how to obtain the motional current i_M of the transducer **902**. The circuit **1700** has all of the circuit elements of the transducer model **1600** plus an additional bridging capacitive element C_B in parallel with the transducer model **1600** of FIG. **16**. However, the value of C_B is selected so that C_1/C_B is equal to a given ratio r. For efficiency, the chosen value for C_B should be relatively low. This limits the current that is diverted from i_M. A variable power source V_T is applied across the terminals **1702** and **1704** of the circuit **1700**, creating a current i_B through the capacitive element C_B, a current i_T flowing into the model transducer **1600**, a current i_C flowing through capacitor C_1, and, finally, the motional current i_M. It then follows that $i_M=i_T-r\cdot i_B$. This is because:

$$i_B = C_B \cdot \frac{\Delta V_T}{\Delta_t} = \frac{C_1}{r} \cdot \frac{\Delta V_T}{\Delta t} \text{ and } i_C = C_1 \cdot \frac{\Delta V_T}{\Delta t}$$

Therefore, $i_C=r\cdot i_B$ and, substituting for i_C in the equation $i_M=i_T-i_C$, leads to: $i_M=i_T-r\cdot i_B$.

Now, by knowing only the total current and measuring the current through the bridge capacitor i_B, variations of the transducer's motional current i_M can be identified and regulated. The driver circuit, represented by block **2708** and the transformer **2710** in FIG. **27**, is included in the push-pull switching amplifier **1010** of FIG. **10**. The driver circuit, then, acts as a current controller and regulates the motional current i_M by varying an output of the driver circuit based on the product of the current flowing through the bridge capacitance C_B multiplied by the ratio r subtracted from a total current i_T flowing into the transducer **902**. This regulation maintains a substantially constant rate of movement of the cutting blade portion of the waveguide **1502** across a variety of cutting loads—something that has not been possible to date. In one exemplary embodiment, sensing circuits **2714** measure the motional voltage and/or motional current. Current and voltage measuring devices and circuit configurations for creating voltage meters and current meters are known in the art. Values of current and voltage can be determined by the present invention in any way now known or later developed, without limitation.

Regulation of the motional current i_M is a true way to maintain the integrity of the instrument and ensure that it will operate at its peak performance under substantially all conditions expected in an operating environment. In addition, such regulation provides these advantages within a package small enough and light enough to be easily held in one hand—a configuration that has never occurred in the field.

c. Transducer Circuit Model

FIG. **18** shows another embodiment of the present invention, where the transducer **902** is schematically represented as a parallel configuration of a resistive element R, an inductive element L, and a capacitive element C_4. An additional capacitive element C_3 is in a series configuration between an input **1702** and the parallel configuration of the resistive element R, the inductive element L, and the capacitive element C_4. This parallel representation models the action of the transducer in a so-called "antiresonant" mode of operation, which occurs at a slightly different frequency. A transducer voltage V_T is applied between the input terminals **1702**, **1704** of the transducer **902**. The transducer voltage V_T is split between a voltage V_C across capacitive element C_3 and a motional voltage V_M across the parallel configuration of the resistive element R, the inductive element L, and the capacitive element C_4. It is the motional voltage V_M that performs the work and causes the waveguide **1502** to move. Therefore, in this exemplary embodiment, it is the motional voltage that is to be carefully regulated.

d. Parallel Circuit Model

FIG. **19** shows an exemplary embodiment of an inventive circuit configuration **1900** according to the present invention including the transducer model **1800** of FIG. **18**. The circuit configuration **1900** adds to the transducer model **1800** three additional capacitive elements C_5, C_6, and C_7. Capacitive element C_5 is in series with the transducer model circuit **1800** of FIG. **18** while the capacitive elements C_6 and C_7 are in series with one another and, together, are in parallel with the series combination of the capacitive element C_5 and the transducer circuit model **1800**.

This circuit is analogous to a Wheatstone bridge measuring instrument. Wheatstone bridge circuits are used to measure an unknown electrical resistance by balancing two legs of a bridge circuit, one leg of which includes the unknown component. In the exemplary circuit configuration shown in FIG. **19**, a motional voltage V_M, which equals V_T-V_C, is the unknown. By determining and regulating the motional voltage V_M, the inventive configuration allows a consistent waveguide movement to be maintained as set forth below.

Advantageously, the capacitive element C_7 is selected so that its value is a ratio A of capacitive element C_3, with A being less than one. Likewise, the capacitive element C_6 is selected so that its value is the same ratio A of the capacitive element C_5. The ratio of C_5/C_3 is also the ratio A.

Because the ratio of C_3/C_7 is A and the ratio of C_5/C_6 is also A, the bridge is balanced. It then follows that the feedback voltage V_{fb} divided by the motional voltage V_M is also the ratio A. Therefore, V_m can be represented as simply $A\cdot V_{fb}$.

If the voltage across the model transducer **1800** is still V_T, an input voltage V_{in} equals V_T plus the voltage V_B across the capacitive element C_5. The feedback voltage V_{FB} is measured from a first point located between capacitive elements C_6 and C_7 and a second point located between the transducer and the capacitive element C_5. Now, the upstream components of the TAG assembly **303** act as a voltage controller and vary the power V_{in} to maintain a constant feedback voltage V_{fb}, resulting in a substantially constant motional voltage and maintaining a substantially constant rate of movement of the cutting blade portion of the waveguide **1502** across a variety of cutting loads. Again, unlike the prior art, the present invention is not simply regulating the input voltage V_{in}, it is varying the input voltage V_{in} for the purpose of regulating the motional voltage V_M—which is novel in the art.

e. Transformer Series Monitoring

FIG. **20** shows another exemplary embodiment of the present invention where the transducer **902** is of the circuit configuration shown in FIG. **16**. The configuration of FIG. **20** works similarly to that shown in FIG. **17** and as described above in connection with FIG. **17**. However, in this circuit configuration **2000**, a pair of transformers **2004** and **2008** is used to determine and monitor the motional current I_M. In this exemplary embodiment, a primary winding **2002** of the first transformer **2004** is in a series configuration with a bridge capacitor C_B. Similarly, a primary winding **2006** of the second transformer **2008** is in a series configuration with the model transducer **1600**. The leads **2010**, **2012** of the secondary winding **2014** of the first transformer **2004** are coupled through a resistor R_2. The leads **2016**, **2018** of the secondary winding **2020** of the second transformer **2008** are coupled through a resistor R_1. In addition, the first lead **2010** of the secondary winding **2014** of the first transformer **2004** is directly connected to the first lead **2016** of the secondary winding **2020** of the second transformer **2008**.

Current i_B passing through the primary winding **2002** of the first transformer **2004** induces a current in the secondary winding **2014** of the first transformer **2004**. Similarly, the currents including i_C passing through the capacitive element C_1 of the transducer **1600** and the motional current i_M of the transducer **1600** combine and go through the primary winding **2006** of the second transformer **2008** to find ground **2022**. The current in the primary winding **2006** induces a current on the secondary winding **2020**. As noted by the dots ("●") on the transformers **2004**, **2008**, the secondary windings **2014**, **2020** are in opposite directions from one another, with reference to the primary windings **2002**, **2006**, respectively, and induce a voltage V_{fb} across resistors R_1 and R_2. By selecting values for R_1 and R_2 so that a ratio of R_1/R_2 is equal to the ratio of the values C_B/C_1, the feedback voltage V_{fb} will always be proportional to the motional current i_M. Now, the upstream components of the generator **904** act as a voltage controller and vary the input power (V_{in} and I_{in}) to maintain a constant feedback voltage V_{fb}, resulting in a substantially constant motional current i_M and maintaining a substantially constant rate of movement of the cutting blade portion of the waveguide **1502** across a variety of cutting loads. Again, unlike the prior art, the present invention is not simply regulating the input voltage V_{in}, it is varying the input current for the purpose of regulating the motional current i_M—which is novel in the art.

An alternative embodiment, which is not illustrated, substitutes use of the transformers **2004**, **2008** with resistors. For example, with regard to FIG. **19**, the capacitors C_6 and C_5 can be replaced with resistors, which are used to measure the currents I_b and I_t.

f. Transformer Parallel Monitoring

FIG. **21** shows another exemplary embodiment of the present invention where the model transducer **1800** is modeled by the circuit configuration shown in FIG. **18**. The configuration of FIG. **21** works similarly to that shown in FIG. **19** and as described above in connection with FIG. **19**. However, in this circuit configuration **2100**, a transformer **2110** is used to determine and monitor the motional voltage V_M of the transducer **1800**. In this embodiment, a primary winding **2106** of the transformer **2110** is in a series circuit configuration with an inductive element L_2 and a capacitive element C_1. A voltage V_{in} is applied across input leads **2102**, **2104** of the circuit formed by the primary winding **2106** of the transformer **2110**, the inductive element L_2, and the capacitive element C_1. A current through the primary winding **2106** induces a corresponding current in the secondary winding **2108** of the transformer **2110**. The secondary winding **2108** of the transformer **2110** is in a parallel configuration with a combination of the transducer **1800** and a bridge capacitor C_B. The two components forming the combination are in a series configuration.

In this embodiment, the secondary winding **2108** is tapped at a point **2112**. By tapping the secondary winding **2108** at a point where a first portion of the secondary winding **2108** has m turns and a second portion of the secondary winding **2108** has n turns (where n is less than m), a selectable percentage of the induced voltage on the secondary winding **2108** appears from point **2112** to ground **2114**.

Again, this circuit is analogous to a Wheatstone bridge measuring instrument. One leg is the first secondary winding m, the second leg is the second secondary winding n, the third leg is the transducer model **1800**, and the fourth leg is the capacitor C_B. In the instant circuit configuration shown in FIG. **21**, the voltage V_M is the unknown. By determining and regulating the motional voltage V_M, a consistent waveguide movement is maintained.

By selecting a value of the bridge capacitor C_B to be less than the transducer capacitance C_3 by the same percentage that the number of turns n is less than the number of turns m (i.e., $m/n=C_3/C_B$), the value of a feedback voltage V_{fb} will reflect the motional voltage V_M. The invention can determine whether the motional voltage V_M is changing by monitoring the feedback voltage V_{fb} for changes.

By using the equivalent-circuit transducer model **1800**, which models a parallel-resonant (or "anti-resonant") transducer, the transducer may be driven in the parallel resonant mode of operation, where motion is proportional to voltage. The advantage of this mode of operation is that the required constant-voltage-mode power supply is simpler to design and safer to operate than a constant-current-mode power supply. Also, because the transducer has a higher impedance when unloaded (rather than a lower impedance when unloaded in the series-resonant mode of operation), it naturally tends to draw less power when unloaded. The parallel-resonant mode of operation, however, is more difficult to maintain because the resonant bandwidth is narrower than that of the series-resonant mode and has a slightly different natural resonant frequency; hence, the mechanical components of the device must be specifically configured to operate at either the series resonant or parallel-resonant mode of operation.

The present invention controls the voltage and varies the power V_{in} to maintain a constant feedback voltage V_{fb}, resulting in a substantially constant motional voltage V_M and maintains a substantially constant rate of movement of the cutting blade portion of the waveguide **1502** across a variety of cutting loads. Again, unlike the prior art, the present invention is not simply regulating the input voltage V_{in}, it is varying the input voltage V_{in} for the purpose of regulating the motional voltage V_M—which is novel in the art.

In accordance with the present invention, the microcontroller **1005** in the TAG **303** monitors the feedback signal through motional bridge **1014** to generate the signal that goes to the primary side of the transformer **1010**. The TAG microcontroller **1006** calculates (in the CLA **912**) the phase difference between these signals and adjusts the NCO **1008** output to make the phase difference equal to zero. When the motional feedback signal is in phase with the output of the push-pull switching amplifier **1010**, the system is operating at series resonance. The phase and magnitude of the motional feedback signal is computed using a discrete Fourier transform (DFT). In one exemplary embodiment of the present invention, the phase reference for the DFT computation is the drive signal for the push-pull amplifier **1010**. The frequency can be changed to cause the push-pull drive signal to be in phase with the motional feedback signal.

According to one exemplary embodiment of the present invention, if the phase of the motional feedback signal is positive, it is an indication the running frequency is below the resonant frequency and the running frequency should be increased; if the phase is negative, it is an indication the running frequency is above the resonant frequency and the running frequency should be decreased; if the phase is close to zero, the running frequency is close to the resonant frequency of the transducer **902** and waveguide **1502**. In the generator **904**, the NCO **1008** (utilizing DDS) is used to alter the frequency appropriately.

Significantly, the NCO **1008** outputs a clock to the CPU's external clock input at a frequency, for example, 6 times less that the operating frequency of the TAG microcontroller **1006**. The external frequency input is fed into the processor's Phase Lock Loop (PLL) and multiplied by a factor of 6 to obtain the CPU's SYSCLK. The NCO **1008** is controlled by the processor through an SPI interface. The SPI interface is used to write a 32-bit divisor to the NCO **1008** that is used to divide the 25-MHz fixed frequency clock to obtain the desired output frequency. By controlling the DDS **2200**, the TAG provides synchronized operation of hardware with the oscillation frequency. In other words, to the main processor **914**, it appears as though the frequency is constant, thereby simplifying the sampling and calculation of the motion feedback phase.

VII. Startup Operation

Startup conditions are different than those during steady state operation, which is described in detail in the following section. At startup, the waveguide **1502** is initially at rest and, therefore, there is no waveguide motion. Accordingly, there is no immediate, ascertainable motional feedback signal that can be used to determine the composite resonant frequency of the transducer **902** and waveguide **1502**. As a result, the inventive system has an ability to operate in a different mode during an initial startup period than during steady state.

A startup procedure according to an exemplary embodiment of the present invention is represented in the process flow diagram of FIG. **72**, which illustrates an interchange between the battery controller **703** and the generator **904** of the TAG assembly **303**. In this particular embodiment, as described in detail below, the relationship between the battery controller and generator can be described as a "master-and-slave" relationship, as the battery controller issues all commands to the generator **904** and the generator **904** receives all of its instructions from the battery controller **703**. Alternatively, the generator **904** of the TAG assembly **303** could act as the "master" and issue all commands to the battery controller **703**, or, the generator **904** of the TAG assembly **303** and the battery controller **703** may function as peers.

Prior to activation, both the battery controller **703** and the generator **904** are idle at steps **7201** and **7202**, respectively. In step **7203**, the battery controller **703** is awakened out of its idle condition, for example, by the user squeezing the button/trigger **4608**. To begin the exchange between the battery controller **703** and the generator **904**, the battery controller **703** relays a signal, such as an "ULTRASOUND ON" command **7205**, to the generator **904** using the communication lines **602***a-n* (i.e., Comm+/Comm−). If operating properly, the generator acknowledges the command **7205** received from the battery controller **703** and, in return, signals a positive response **7204**, such as an "ULTRASOUND ON" response, to the battery controller **703** using the communication lines **602***a-n* (i.e., Comm+/Comm−). However, if the generator **904** does not positively respond to the initial command **7205** from the battery controller **703** before a specific period of time has lapsed (e.g., 10 ms), the battery controller issues a fault condition at step **7207**, such as a "FAILURE TO START" condition, and terminates the operation cycle at step **7209**. At such time, appropriate indicators can be actuated.

a. Current and Amplitude Control

If there is a successful acknowledgment by the generator **904** of the "ULTRASOUND ON" command **7205** sent from the battery controller **703**, the microcontroller **1106** in the battery controller **703** initiates a process for quickly and safely advancing the current rate in the TAG assembly **303** resulting in a resonant motion output from the TAG assembly **303** to the waveguide **1502**. Advancement proceeds from an idle condition to a level predicted to be within a "ballpark window" for producing an ascertainable motional feedback signal and achieving a beginning resonant frequency condition. As shown in FIG. **11**, the microcontroller **1106** in the battery controller **703** has two processing units. A first processing unit, the Control Law Accelerator ("CLA") **1116**, handles a first, inner, current-control loop **2601** (see FIG. **26**), and the second processing unit, a main processor **1118**, handles a second, outer, amplitude-control loop **2602** (see FIG. **26**). At the outset, in step **7213**, microcontroller **1106** turns on the buck power supply **1114** and initializes the CLA **1116**. The CLA **1116** uses a proportional-integral-derivative ("PID") control algorithm to compute a new duty cycle value for the Pulse Width Modulators ("PWMs") that are driving the two-phase buck converter **1114**. At step **7215**, the battery controller **703** starts the PWMs and begins, at step **7211**, using a fast, non-linear PID control loop, to increase the output voltage of the DC-DC converter **1202**. The increasing output voltage causes a corresponding increase in the input current to the push/pull amplifier **1010** of the generator **904**. At step **7217**, the output voltage increases, or is otherwise modified, until, at step **7219**, the actual, measured input current reaches a predetermined reference current level, referred to herein as "I_{ref}." I_{ref} is a calibrated value that is predicted to create a driving wave output from the transducer **902** that will achieve a displacement of the waveguide **1502** and place the resulting amplitude near a value sufficient to reach the target resonant frequency. I_{ref} is initially set by the battery microcontroller **703** in step **7225**. This calibrated value for I_{ref} may be stored inside the TAG assembly **303** and read by the battery microcontroller **703** upon establishment of the communication link **7204**. Simply put, I_{ref} is a way to not overdrive the system during startup so that with low motion during startup, the system does not overreact and overshoot. I_{ref} is the estimated current to drive the system at the target displacement. When the system gets close to target displacement, then the amplitude control takes over.

Table 1 below illustrates an example of a non-linear PID control loop or algorithm in accordance with the present invention, whereby the output voltage level is modified until the actual, measured input current reaches the reference current, I_{ref}. In this example, the non-linear PID control loop divides the percent error of the actual, measured input current versus the reference current I_{ref} into 5% bins, which are shown below as constants G_0 through G_n (where "n" is some number of the last step prior to reaching I_{ref}). Each bin has its own non-linear tuning coefficients (e.g., K_p, K_i, and K_d). The non-linear tuning coefficients allow for the output voltage and, in turn, the actual input current, to initially advance quickly towards the reference current point I_{ref} when the input current is far away from the reference current point, and then slowly reach the reference current point I_{ref} once the input current value is close to reaching the reference current point. As a result, the system is less prone to being disturbed by noise. In this particular example, the non-linear PID within the CLA **1116** shapes the overshoot to no more than 15% greater than I_{ref}. It is desirable to have the control loop maintain current but not to allow over current for any significant time; in other words, the loop must make the current retract from an overcurrent state quickly. Accordingly, the non-linear PID loop of the CLA **1116** shapes the increase of the output voltage and input current in such a way that the input current advances quickly and accurately to the desired reference current level I_{ref}, but does so in such a way that is stable and avoids a dangerous "overcurrent" condition.

TABLE 1

Gain constant:	G_0	G_1	G_2		G_n		G_n	G_1	G_0
Percent away from I_{ref}:	50%	45%	40%	...	5%	I_{ref}	-5%	-10%	-15%

In the meantime, while the input current is steadily increasing under the control of the battery microcontroller **1106**, the initial signal, i.e., the "ULTRASOUND ON" command **7205** from the battery controller **703**, received by the generator, causes the TAG microcontroller **1006** to begin its own initialization process in parallel with the operation of the battery controller **703**. As set forth above with regard to FIG. **9**, the microcontroller **1006** in the TAG assembly **303** has two independent processing units: the CLA **912** and the main processor **914**. Referring back to FIG. **72**, at steps **7200** and **7206**, upon receiving the initial command **7205** from the battery controller **703**, the TAG microcontroller **1006** initializes the CLA **912** and starts the ultrasound PWMs that drive the ultrasonic frequency at a frequency within the operating frequency range of the waveguide and transducer. At this initial start up stage, any motional feedback signal that is present is weak and, therefore, it is desirable to use a high gain amplifier to provide a higher signal level because the signal level is initially very small. At step **7208**, as the input current from the battery assembly is increasing, the amplitude (i.e., the displacement of the mechanical motion) is incrementing proportionally until it reaches a set point or level within 20% of a "target amplitude," which should produce a motional feedback signal and place the TAG assembly **303** in a "ballpark window" for achieving the resonant frequency. The "target amplitude" is a pre-determined, safe, threshold level. It is undesirable to surpass this threshold level and, when surpassed (e.g., by 10-12%), indicates an "over-amplitude" condition that is undesirable and causes the device to initiate a fault condition and control shutdown.

The battery controller **703** closely monitors the amplitude to regulate the displacement level of the TAG assembly **303**. The battery controller **703** issues a command **7221** at frequent intervals (e.g., every 4 ms), such as an "AMPLITUDE REQ" command, to the TAG assembly **303** using at least one of the communication lines **602***a-n* (e.g., Comm+/Comm−). In response, the battery controller **703** receives a signal **7210**, through at least one of the communication lines **602***a-n* (e.g., Comm+/Comm−), such as an "AMPLITUDE REQ" response, from the TAG assembly **303**, which provides the battery controller **703** with a measurement of the displacement level of the TAG assembly **303**. At each interval that a measurement of the displacement level is determined by the battery controller **703**, the battery microcontroller **1106**, at step **7223**, makes one of several possible determinations based upon the displacement measurement. If the amplitude level has reached the level of within 20% of the "target amplitude" or, effectively, 80% of the "target amplitude," in step **7227** the power control is switched from the inner, current-control loop **2601** to the outer, amplitude-control loop **2602**, which is described in further detail below. If the amplitude level has not yet reached 80% of the "target amplitude," in step **7229**, the current control loop will maintain the current at the reference current level I_{ref} until the amplitude reaches the 80% point.

However, if the amplitude level still has not reached the 80% point within a set period of time (e.g., 250 ms), this indicates a "low amplitude" fault condition 7231 that may be due to, for example, a stalled blade of the waveguide **1502**. In response, the battery microcontroller **1106** terminates the operation cycle at step **7209** and issues, for example, an "ULTRASOUND OFF" command **7233** to the generator **904**. In return, the generator **904** relays a response **7212**, such as an "ULTRASOUND OFF" response, indicating that it has ceased active operation. If the potentially dangerous condition occurs in which the amplitude level has actually surpassed the level of within 20% of the "target amplitude," the battery microcontroller **1106** immediately issues a fault condition 7235 and terminates the operation cycle at step **7209**, as described above, due to this "over-amplitude" condition.

b. Frequency Lock

Now, referring to FIG. **72**A, as previously mentioned, upon initialization, the TAG microcontroller **1006** controls the frequency of the signal that drives the transducer **902** based upon its detection of the motional feedback signal. At the beginning of the startup process, in step **7206**, the operating frequency is set at a fixed value that is within the operating frequency range of the transducer **902** and waveguide **1502** (e.g., 55.2 kHz). If present at that set frequency, a motional feedback signal from the bridge circuit is routed to a high and low gain buffer. Each of these signals is fed into the analog-to-digital converter ("ADC") **908** of the microcontroller **1006** in the TAG assembly **303**. Initially, the high-gain, buffered-feedback signal is selected as the motional feedback signal will initially be small. A main function of the CLA **912** is to take the output from the ADC, perform the Discrete Fourier Transform ("DFT") calculations, and pass the results to the main processor **914**. Shown as step **7218**, the results from the DFT calculations are the phase and magnitude of the motional feedback ("MF") signal, as well as the real and imaginary terms for the signal.

A tuning loop is called once per ultrasound cycle. If, at step **7214**, it is determined that a valid motional feedback signal does not exist at the set frequency, the system simply waits until there is a valid motional feedback signal. However, if a fixed period of time has been exceeded as determined by a cycle timeout timer, and there is still no valid motional feedback signal, a cycle activation limit "timeout" is triggered at step **7216** and the generator **904** turns off.

Initially, at step **7222**, the system employs a high-gain-buffered A-to-D channel such that the high-gain-buffered feedback signal is selected. This allows the system to lock at a lower motional feedback signal level. A determination of whether or not the motional feedback signal has reached a defined "THRESHOLD" value is made at step **7220**. If the motional feedback signal has reached the defined "THRESHOLD" value, the amplitude of the motional feedback signal has increased to the point that a valid motional feedback signal has emerged from any obstructive noise such that the DFT calculations in the CLA **912** are reliable. At this point, in step **7224**, the system switches to the low-gain channel. However, should the system fall below this "THRESHOLD" value, the A-to-D channel can switch back to the high-gain channel as shown in step **7226**. By having the ability to switch to the low-gain channel at this point, a higher resolution A/D converter is beneficially not required.

At step **7228**, if the motional feedback signal is above a starting threshold value, the generator **904** enters a frequency-tuning mode for locking the set frequency onto the resonant frequency of the TAG assembly **303** in parallel with the current and amplitude controls described above. In accordance with an exemplary embodiment of the present invention, the process for achieving resonant frequency is not a process of sweeping for the optimum frequency, but rather is uniquely a tracking or tuning process for locking onto the optimum frequency. However, the present invention may also employ a frequency sweeping mode, whereby the initial operating or set frequency is chosen to be at a lower boundary of the "ballpark window" of the predicted resonant frequency and is steadily incremented until it reaches the resonant frequency or vice versa.

Once frequency tuning mode is entered, the main processor **914** of the TAG microcontroller **1006** uses the results of the DFT calculation (i.e., the phase and magnitude of the motional feedback signal) to control the running frequency of the generator. The tuning algorithm is divided into two states: STARTING and LOCKING. In the STARTING phase at step **7230**, a determination is made of whether or not the motional feedback signal has reached a defined "STARTUP THRESHOLD" value. If the motional feedback signal has reached the defined "STARTUP THRESHOLD" value, the amplitude of the motional feedback signal has increased to the point that the system can actively begin moving towards resonance at step **7232**. If the determination at step **7230** is that the motional feedback signal has not reached the defined "STARTUP THRESHOLD" value, the process moves to step **7234**. At step **7234**, the STARTING phase simply waits until the point is reached whereby there is a large enough motional feedback signal to allow locking.

In the LOCKING phase **7236**, the sine of the phase offset between the motional feedback signal and the driving signal is used along with the differential of the sine to determine the size and direction of the frequency step to adjust the output frequency to move the system to resonance. Although the phase is naturally a tangent function, the sine of the phase is used to determine the frequency step because it is bounded by the value ±1 and closely approximates the phase value at small angles, whereas a tangent function has the undesirable, unbounded range of ±∞.

In step **7238**, a PID loop is used to calculate the frequency step in either a plus or minus direction. The PID loop is non-linear, whereby the value of the sine is used to determine a bin number. That bin number is used as an index to access the tuning coefficients used by the PID. An index table contains the proportional gain, the integral gain, and the differential gain. In addition, the entry sine value to enter a bin differs from the value to exit a bin. This introduces hysteresis to prevent oscillations near the bin transitions.

As previously explained, a non-linear PID is used to achieve a rapid frequency lock. Table 2 below illustrates an example of a non-linear, asymmetric PID loop or algorithm in accordance with the present invention whereby the size in frequency step is staggered until it reaches the target resonance frequency, f_{res}. In this example, the gain constants PID_0 through PID_n (whereby "n" is some number of the last frequency step prior to reaching f_{res}) are separated by non-linear increments. The gain values have been chosen to move the system toward resonance quickly when the system is far from resonance and slowly when the system is close to or at resonance. It is important to step slowly when close to or at resonance in order to avoid inducing frequency modulation, which would cause undesirable effects on the amplitude. During startup, the value for the maximum frequency step size is greater than during steady state operation; it is, for example, set to 8 Hz. If the phase is positive, it is an indication that the running frequency is below the resonant frequency of the transducer and needs to be increased. If the phase is negative, it is an indication the running frequency is above the resonant frequency and the running frequency should be decreased. If the phase is close to zero, the running frequency is close to the resonant frequency of the transducer **902** and waveguide **1502**. The numerically controlled oscillator **1008** utilizing direct digital synthesis is used to change the frequency at step **7240**.

TABLE 2

Gain Constant:	PID_0	PID_1	PID_2	$PID_3 \cdot\cdot PID_n$	$PID_n \cdot\cdot PID_3$	PID_2	PID_1	PID_0
Driving Frequency:	f_{min}				f_{res}			f_{max}
Phase$_{(sine\ func.;\ 90°\ shift)}$:	+1	+0.6	+0.4	+0.1 +.03	0 -0.2 -0.4	-0.6	-0.8	-1

The DDS **2200** (see FIG. **22**) provides synchronized operation of hardware with the oscillation frequency. In other words, to the main processor **914**, it appears as though the frequency is constant. Here, the clock frequency of the main processor **914** is a multiple of the oscillation frequency. The invention alters the PWM frequency in a unique and novel way. With the invention, PWM is performed inside the main processor **914**. Because of this, the present invention actually increases/decreases the frequency of the main processor **914**—which has not been done before. The A/D converter **908** adjustments are automatic as well because the A/D converter **908** exists inside the microcontroller **1006**. This inventive technique can be analogized to a singer adjusting a speed of a metronome to match the singer's tempo rather than, as is conventionally done, the singer changing her/his tempo to match the metronome.

At anytime during operation of the device, if the frequency reaches a pre-set minimum or maximum frequency limit, f_{min} and f_{max}, respectively, the generator **904** turns off and a fault condition is triggered, as shown in step **7242**. Exemplary lower and upper frequency limits for the invention are 54 kHz and 58 kHz, respectively. A number of various conditions can cause the frequency to reach the minimum or maximum limit, including breakage of a component (such as the waveguide

1502) or a situation in which the waveguide **1502** is under such a heavy load that the device is not able to input the amount of power needed to find resonance.

Once frequency lock is achieved, the transition begins into steady state operation.

VIII. Steady State Operation

During steady state operation, the objective is to maintain the transducer and waveguide at resonant frequency and to control the displacement in response to any drifting that occurs as a result of a load on the waveguide **1502** during use of the device. When the transducer **902** and waveguide **1502** are driven at their composite resonant frequency, they produce a large amount of mechanical motion. The electrical energy from the battery is, in this state, converted into a high voltage AC waveform that drives the transducer **902**. The frequency of this waveform should be the same as the resonant frequency of the waveguide **1502** and transducer **902**, and the magnitude of the waveform should be the value that produces the proper amount of mechanical motion.

a. Amplitude Control

At resonance, the displacement is approximately proportional to the transducer current, and the transducer current is approximately proportional to the input current to the push/pull amplifier **1010**. With constant current operation to maintain constant displacement, the output voltage will vary with a varying load. In other words, the voltage will increase if the output power requirement increases and vice versa.

As described above in relation to the startup process, shown in FIG. **26** are two control loops, an inner, current control loop **2601** and an outer, amplitude control loop **2602** for uniquely regulating the amplitude of the driving wave input to the transducer **902**. The current control loop **2601** regulates the current from the battery assembly **301** going into the push/pull amplifier **1010**. The amplitude control loop **2602** compensates for load differences or any other changes that occur in the transducer and/or waveguide. To accomplish this goal, the amplitude control loop **2602** utilizes the motional feedback signal to generate the desired reference current level, "I_{ref}," that is used by the current control loop **2601** to alter the output voltage of the DC-DC converter as described above. To avoid interference-type interactions between the two loops, the current control loop **2601** operates at a higher frequency than the amplitude control loop **2602**, e.g., approximately 300 KHz. The amplitude control loop **2602** typically operates, for example, at a frequency of 250 Hz.

To determine the desired reference current level, I_{ref}, the present amplitude value is subtracted from the desired "target amplitude" to generate an amplitude percent error signal. This amplitude percent error signal is the input into the PID control algorithm of the amplitude control loop **2601** for generating the new, desired reference current level "I_{ref}," based upon the operating conditions being experienced by the transducer **902** and waveguide **1502** at that particular time. In other words, the amplitude control loop **2602** changes the target or reference current value for the CLA **912** of the current control loop **2601** to reach the desired amplitude based on the percent error calculation. In this way, the output power is altered based on the variable need of the transducer **902** and waveguide **1502**. The main processor **1118** of the battery controller **703** checks the new reference current value to make sure that it is not greater than the maximum output current value.

Based upon the new target or reference current value, I_{ref}, that is set by the amplitude control loop **2602**, the current control loop **2601** proceeds to change the output voltage and input current to the push/pull amplifier **1010**. A measurement of the actual current level **2603** of the battery pack output is fed into the ADC **1120** of the battery microcontroller **1106** (shown in FIG. **11**). The CLA **1116** takes the value from the ADC **1120** and subtracts it from the target or reference input current level I_{ref} to generate the current error signal. As described above, the CLA **1116** uses the PID control algorithm to compute a new duty cycle value for the PWMs that are driving the two-phase buck converter **1114**. The CLA **1116** also computes a maximum PWM duty cycle to limit the output voltage. The algorithm to compute the maximum duty cycle uses the measured battery voltage and assumes the buck converter **1114** is operating in continuous conduction mode.

It is noted that, by utilizing amplitude control, rather than only looking at the current for steadying the amplitude, the present invention uniquely allows for finely adjusting the output of the transducer based on the motional feedback signal, achieving a more precise amplitude control. The use of a current control loop allows for faster initial response that would not be possible with amplitude control alone. Also, having the two loops provides for redundancy and individual calibration of the transducer and generator during manufacture. This "amplitude calibration factor" is critical for dialing out a variation in the electrical and mechanical variations in the transducer/piezoelectric crystals and for adjusting for variation in the electrical components of the generator magnitude feedback system. Within the generator, through the analog-to-digital converters, the feedback voltage is converted with this calibration factor to result in a magnitude value that is directly related to displacement. During the calibration process, this calibration value is adjusted while measuring the actual system output displacement. This adjustment pairs a given transducer and generator together so that, as a system, they will develop the proper displacement. Defaults for this value is intentionally set low as a safety mechanism should the adjusted values be lost, corrupted, or inadvertently not programmed. In this way, the default displacement will be lower than the target, resulting in slower but still effective tissue performance. This calibration scheme simplifies manufacturing and reduces the burden of controlling tolerances of the transducer and the generator. Furthermore, because this calibration is done entirely in software, no additional adjustment of physical parts is required either in the transducer or the generator. In effect, two control loops are being used to regulate the amplitude of the driving wave input to the transducer, which provides synchronized operation of the hardware with the oscillation frequency. Redundancy is useful to ensure the device is operating correctly. A malfunction in one loop will usually be detectable because the other loop will be unable to operate properly and the improper operation of either loop is usually detectable. Improper operation can be caused by a hardware fault. The proper operation of both loops requires measurement of both current and amplitude. Different hardware is used to measure amplitude and current. In one embodiment, the battery microcontroller **1106** measures current and the TAG microcontroller **1006** measures amplitude. As the transducer heats up, the capacitance of the transducer and the coupling coefficient will shift and the displacement of the system will decline slightly. This change in temperature also comes with a shift in frequency. By monitoring the frequency, it is possible to provide an offset to more tightly control the displacement through heavy use. This can be accomplished with a comparison to the frequency at startup or to an absolute frequency reference. Alternatively, other measurable characteristics of the transducer can be used to control this offset. Alternatively, the amount of energy put into the transducer can be used to estimate the change and adjust accordingly.

b. Frequency Control

In a similar operation to the initial frequency lock performed during the startup process, the main processor **914** of the generator **904** uses the results of the DFT calculation to adjust the running frequency of the generator **904** based on the phase of the motional feedback signal in order to maintain a resonant frequency during steady state operation. The motional feedback signal from the bridge circuit is proportional to and in phase with the motion of the transducer **902** and waveguide **1502**. When the motional feedback signal is in phase with the output of the push/pull switching amplifier **1010**, the system is operating at the series resonance. Again, the phase and magnitude of the motional feedback signal is computed using a Discrete Fourier Transform ("DFT"). The phase reference for the DFT computation is the drive signal for the push/pull amplifier **1010**. The frequency is, then, simply changed to cause the push/pull drive signal to be in phase with the motional feedback signal.

The DFT calculation is simplified and made more accurate if the ADC sample time interval is exactly an integer multiple of the output frequency period. This technique is referred to herein as "coherent sampling." In one exemplary embodiment, the signals are sampled 12 times per output cycle such that the CLA **912** is sampling the motional feedback signal at 12 times the ultrasonic frequency. With coherent sampling, there are exactly 12 samples per cycle with each occurring at the same point in time relative to the phase of the drive signal. As shown in FIG. **9**, the ADC sample clock is generated internally in the TAG microcontroller's **1006** system clock **916**. Accordingly, for coherent sampling, the system clock **916** needs to be synchronized to the output. The PWM signal driving the metal-oxide field-effect transistors (MOSFETs) that, in turn, generate the output waveform, is also generated internally from the system clock **916**. One exemplary embodiment of the present invention generates the system clock **916** from the DDS **1008**. Advantageously, as the output frequency changes, the system clock **916** also changes.

It is also desirable not to sample shortly after the MOSFETs are switched on or off. This is when there is the largest amount of noise present in the system. Offsetting the sample time to avoid sampling shortly after the MOSFETs switch on or off minimizes the affect of transistor switching noise on the ADC sample. The two PWM outputs employ a deadband to ensure that both MOSFETs are never activated at the same time.

X. Simplified Circuit Block Diagram

FIG. **27** shows a simplified block circuit diagram illustrating another exemplary electrical embodiment of the present invention, which includes a microprocessor **2702**, a clock **2730**, a memory **2726**, a power supply **2704** (e.g., a battery), a switch **2706** (e.g., a MOSFET power switch), a drive circuit **2708** (PLL), a transformer **2710**, a signal smoothing circuit **2712** (also referred to as a matching circuit and can be, e.g., a tank circuit), a sensing circuit **2714**, a transducer **902**, and a waveguide assembly **304**, which terminates at an ultrasonic cutting blade **1520**, referred to herein simply as the waveguide **1502**.

One feature of the present invention that severs dependency on high voltage (120 VAC) input power (a characteristic of all prior-art ultrasonic cutting devices) is the utilization of low-voltage switching throughout the wave-forming process and the amplification of the driving signal only directly before the transformer stage. For this reason, in one exemplary embodiment of the present invention, power is derived from only a battery, or a group of batteries, small enough to fit either within the handle assembly **302**. State-of-the-art battery technology provides powerful batteries of a few centimeters in height and width and a few millimeters in depth. By combining the features of the present invention to provide an entirely self-contained and self-powered ultrasonic device, the capital outlay of the countertop box **202** is entirely eliminated—resulting in a significant reduction of manufacturing cost.

The output of the battery **2704** is fed to and powers the processor **2702**. The processor **2702** receives and outputs signals and, as will be described below, functions according to custom logic or in accordance with computer programs that are executed by the processor **2702**. The device **2700** can also include a main memory **2726**, preferably, random access memory (RAM), that stores computer-readable instructions and data.

The output of the battery **2704** also is directed to a switch **2706** having a duty cycle controlled by the processor **2702**. By controlling the on-time for the switch **2706**, the processor **2702** is able to dictate the total amount of power that is ultimately delivered to the transducer **2716**. In one exemplary embodiment, the switch **2706** is a MOSFET, although other switches and switching configurations are adaptable as well. The output of the switch **2706** is fed to a drive circuit **2708** that contains, for example, a phase detecting PLL and/or a low-pass filter and/or a voltage-controlled oscillator. The output of the switch **2706** is sampled by the processor **2702** to determine the voltage and current of the output signal (labeled in FIGS. **27** as AD2 V_{In} and AD3 I_{In}, respectively). These values are used in a feedback architecture to adjust the pulse width modulation of the switch **2706**. For instance, the duty cycle of the switch **2706** can vary from about 20% to about 80%, depending on the desired and actual output from the switch **2706**.

The drive circuit **2708**, which receives the signal from the switch **2706**, includes an oscillatory circuit that turns the output of the switch **2706** into an electrical signal having a single ultrasonic frequency, e.g., 55 kHz (referred to as VCO in FIG. **27**). As explained above, a smoothed-out version of this ultrasonic waveform is ultimately fed to the transducer **902** to produce a resonant sine wave along the waveguide **1502**.

At the output of the drive circuit **2708** is a transformer **2710** that is able to step up the low voltage signal(s) to a higher voltage. It is noted that all upstream switching, prior to the transformer **2710**, is performed at low (i.e., battery driven) voltages, something that, to date, has not been possible for ultrasonic cutting and cautery devices. This is at least partially due to the fact that the device advantageously uses low on-resistance MOSFET switching devices. Low on-resistance MOSFET switches are advantageous, as they produce lower switching losses and less heat than a traditional MOSFET device and allow higher current to pass through. Therefore, the switching stage (pre-transformer) can be characterized as low voltage/high current. To ensure the lower on-resistance of the amplifier MOSFET(s), the MOSFET(s) are run, for example, at 10 V. In such a case, a separate 10 VDC power supply can be used to feed the MOSFET gate, which ensures that the MOSFET is fully on and a reasonably low on resistance is achieved. In one exemplary embodiment of the present invention, the transformer **2710** steps up the battery voltage to 120V RMS. Transformers are known in the art and are, therefore, not explained here in detail.

In each of the circuit configurations described and shown in FIGS. **3-12**, **16-21**, and **27**, circuit component degradation can negatively impact the entire circuit's performance. One factor that directly affects component performance is heat. Known circuits generally monitor switching temperatures (e.g., MOSFET temperatures). However, because of the technological advancements in MOSFET designs, and the corresponding reduction in size, MOSFET temperatures are no longer a valid indicator of circuit loads and heat. For this reason, according to an exemplary embodiment, the present invention senses with a sensing circuit **2714** the temperature of the transformer **2710**. This temperature sensing is advantageous as the transformer **2710** is run at or very close to its maximum temperature during use of the device. Additional temperature will cause the core material, e.g., the ferrite, to break down and permanent damage can occur. The present invention can respond to a maximum temperature of the transformer **2710** by, for example, reducing the driving power in the transformer **2710**, signaling the user, turning the power off completely, pulsing the power, or other appropriate responses.

In one exemplary embodiment of the invention, the processor **2702** is communicatively coupled to the end effector **118**, which is used to place material in physical contact with the blade portion **116** of the waveguide **114**, e.g., the clamping mechanism shown in FIG. **1**. Sensors are provided that measure, at the end effector, a clamping force value (existing within a known range) and, based upon the received clamping force value, the processor **2702** varies the motional voltage V_M. Because high force values combined with a set motional rate can result in high blade temperatures, a temperature sensor **2736** can be communicatively coupled to the processor **2702**, where the processor **2702** is operable to receive and interpret a signal indicating a current temperature of the blade from the temperature sensor **2736** and to determine a target frequency of blade movement based upon the received temperature.

According to an exemplary embodiment of the present invention, the PLL **2708**, which is coupled to the processor **2702**, is able to determine a frequency of waveguide movement and communicate that frequency to the processor **2702**. The processor **2702** stores this frequency value in the memory **2726** when the device is turned off. By reading the clock **2730**, the processor **2702** is able to determine an elapsed time after the device is shut off and retrieve the last frequency of waveguide movement if the elapsed time is less than a predetermined value. The device can then start up at the last frequency, which, presumably, is the optimum frequency for the current load.

XI. Battery Assembly—Mechanical

FIG. **28** shows an exemplary embodiment of the battery assembly **301** separate from the handle assembly **302**. The battery assembly **301** includes an outer shell **2802** that comprises a first half **2802***a* and a second half **2802***b*. There is, however, no requirement that the shell **2802** be provided in two halves. In accordance with an exemplary embodiment of the present invention, when the outer shell **2802** is provided in two halves, the first half **2802***a* can be ultrasonically welded to the second half **2802***b* in a clamshell configuration. Ultrasonically welding the two halves of the shell **2802** eliminates the need for gaskets while providing a "hermetic" seal between the components within the shell **2802** and the environment. A "hermetic" seal, as used herein, indicates a seal that sufficiently isolates a compartment (e.g., interior of the shell **2802**) and components disposed therein from a sterile field of an operating environment into which the device has been introduced so that no contaminants from one side of the seal are able to transfer to the other side of the seal. This seal is at least gas-tight, thereby preventing intrusion of air, water, vapor phase H_2O_2, etc. Upon initial assembly, room air will be trapped in the enclosure with whatever moisture is present. This can easily be more moisture than is desirable in an electronics enclosure. Therefore, inclusion of a desiccant system inside the enclosure can serve two purposes. A primary purpose is to absorb any moisture that may ingress over the life of the device, but, if sized appropriately, the desiccant system will also serve to absorb any moisture that is trapped during assembly. Use of the desiccant system, therefore, simplifies assembly and eliminates the need to close the enclosure under any special environments.

FIG. **28** also shows a multi-lead battery terminal assembly **2804**, which is an interface that electrically couples the components within the battery assembly **301** to an electrical interface of the handle assembly **302**. It is through the handle assembly **302** that the battery assembly **301** is able to electrically (and mechanically) couple with the TAG assembly **303** of the present invention. As is explained above, the battery assembly **301**, through the multi-lead battery terminal assembly **2804**, provides power to the inventive ultrasonic surgical cautery assembly **300**, as well as other functionality described herein. The multi-lead battery terminal assembly **2804** includes a plurality of contacts pads **2806***a-n*, each one capable of separately electrically connecting a terminal within the battery assembly **301** to another terminal provided by a docking bay (see FIG. **34**) of the handle assembly **302**. One example of such electrical connections coupled to the plurality of contact pads **2806***a-n* is shown in FIG. **6** as power and communication signal paths **601***a-n*. In the exemplary embodiment of the multi-lead battery terminal assembly **2804**, sixteen different contact pads **2806***a-n* are shown. This number is merely illustrative. In an exemplary embodiment, an interior side of the battery terminal assembly **2804** has a well formed on the molded terminal holder that can be filled with potting materials to create a gas tight seal. The contact pads **2806***a-n* are overmolded in the lid and extend through the potting well into the interior of the battery **301**. Here a flex circuit can be used to rearrange the array of pins and provide an electrical connection to the circuit boards. In the exemplary embodiment shown in FIG. **30**, for example, a 4×4 array is converted to a 2×8 array.

FIG. **29** provides a view of the underside of an exemplary embodiment of the multi-lead battery terminal assembly **2804**. In this view, it can be seen that the plurality of contact pads **2806***a-n* of the multi-lead battery terminal assembly **2804** include a corresponding plurality of interior contact pins **2906***a-n*. Each contact pin **2906** provides a direct electrical coupling to a corresponding one of the contact pads **2806**. FIGS. **28** and **32** show two hemispherical depressions **2810** in the battery casing that, when combined with the hook feature **3302**, a generally longitudinal void, can be used to retain the battery **301** into a charger. Such geometrical features are easy to fabricate and easy to clean and provide a simple way to capture the battery **301** in a charger in a way that does not require the releasing mechanism that normally is used to disconnect the battery **301** from the handle **302**.

In the exemplary embodiment shown in FIGS. **28** to **33**, the multi-lead battery terminal assembly **2804** is potted between the clam shell halves **2802***a* and **2802***b* of the shell **2802**. More particularly, FIG. **29** provides a view of the multi-lead battery terminal assembly **2804** positioned inside an upper portion of the first shell half **2802***a* of the battery assembly **301**. As is shown in the figure, an upper portion of the first shell half **2802***a* forms a mouth **2902** that accepts an outer peripheral edge **2904** of the multi-lead battery terminal assembly **2804**.

FIG. **30** provides an additional view of the interior of the first shell half **2802***a* with the multi-lead battery terminal assembly **2804** inserted within the mouth **2902** of the first shell half **2802***a* and an exemplary embodiment of a first circuit board **3002** having a plurality of contact pads **3006** coupled to the contact pins **2906** of the multi-lead battery terminal assembly **2804**. In such an embodiment, each of the contact pins **2906** is soldered to its respective contact pad **3006** of the circuit board **3002**. The battery assembly **301**, according to exemplary embodiments of the present invention, includes, as is shown in FIG. **31**, in addition to the first circuit board **3002**, additional circuit boards **3102** and **3104**.

In accordance with one exemplary embodiment of the present invention, the multi-lead battery terminal assembly **2804** comprises a flex circuit that converts the illustrated 4×4 array of contact pads **2006***a-n* to two 1×8 arrays of conductors that are coupled to one or more of the circuit boards **3002**, **3102**, **3104**.

In an alternative exemplary embodiment, rather than using a flex connector and soldering to connect the one or more circuit boards **3002**, **3102**, and **3104**, a card edge connector **10701** could provide connectivity between the boards and the multi-lead battery terminal assembly **2804** as shown in FIG. **107**, which is a cross-sectional view of a shell half of the battery assembly **301** beneath a sloping curvature of the exterior surface of the multi-lead battery terminal assembly **2804**. In this exemplary embodiment, the angle of the slope of the multi-lead terminal assembly **2804** is greater than that shown in FIG. **4**. For purposes of illustration, only one of the plurality of interior contact pins **2906***a-n* is depicted. One end of the contact pin **2906** is embedded into the body of the multi-lead battery terminal assembly **2804**. The other end of the contact pin **2906** is formed into an "S"-shaped curve that gives the contact pin a degree of flex and forms an interior groove or channel **10702** between the contact pin and the body of the multi-lead battery terminal assembly **2804**. The inherent flex of the "S"-shaped portion of the contact pin **2906** allows for any of the one or more circuit boards **3002**, **3102**, **3104** to be easily inserted into the interior groove or channel **10702** to establish a direct electrical connection between the contact pin **2906** and one or more traces of the circuit board **3002**, **3102**, **3104**. To maintain this direct connection, a card edge connector **10704** secures the circuit board in place, thereby eliminating any need for soldering the contact pin **2906** to the circuit board. As a result, the features of the card edge connector **10704** are integrated into the underside of the multi-lead battery terminal assembly **2804**. Accordingly, it is easier to remove the boards for troubleshooting and simplifies manufacturing by eliminating solder joints.

Further, more than or less than three circuit boards is possible to provide expanded or limited functionality. As shown in FIG. **31**, the multiple circuit boards **3002**, **3012**, **3104** may be positioned in a stacked architecture, which provides a number of advantages. For example, due to the smaller layout size, the circuit boards have a reduced footprint within the battery assembly **301**, thereby allowing for a smaller battery. In addition, in this configuration, is possible to easily isolate power boards from digital boards to prevent any noise originating from the power boards to cause harm to the digital boards. Also, the stacked configuration allows for direct connect features between the boards, thereby reducing the presence of wires. Furthermore, the circuit boards can be configured as part of a single rigid-flex-rigid circuit to allow the rigid parts to be "fanned" into a smaller volumetric area. According to exemplary embodiments of the present invention, each circuit board **3002**, **3102**, and **3104** provides a specific function. For instance, circuit board **3002** can provide the components for carrying out the battery protection circuitry **702** shown in FIG. **7**. Similarly, the circuit board **3102** can provide the components for carrying out the battery controller **703**, also shown in FIG. **7**. The circuit board **3104** can, for example, provide high power buck controller components. Finally, the battery protection circuitry **702** can provide connection paths for coupling the battery cells **701***a-n* shown in FIGS. **7** and **31**. By placing the circuit boards in a stacked configuration and separating the boards by their respective functions, the boards may be strategically placed in a specific order that best handles their individual noise and heat generation. For example, the circuit board having the high-power buck controller components produces the most heat and, therefore, it can be isolated from the other boards and placed in the center of the stack. In this way, the heat can be kept away from the outer surface of the device in an effort to prevent the heat from being felt by the physician or operator of the device. In addition, the battery board grounds may be configured in a star topology with the center located at the buck controller board to reduce the noise created by ground loops.

The strategically stacked circuit boards, the low thermal conductivity path from the circuit boards to the multi-lead battery terminal assembly, and a flex circuit **3516** are all features that assist in preventing heat from reaching the exterior surface of the device. The battery cells and buck components are thermally connected to the flex circuit **3516** within the handle **302** (i.e., the disposable portion of the device) so that the heat generated by the cells and buck components enter a portion away from the physician's hand. The flex circuit **3516** presents a relatively high thermal mass, due to its broad area of exposure and the advantageous conduction characteristics of the copper, which redirects, absorbs, and/or dissipates heat across a broader area thereby slowing the concentration of heat and limiting high spot temperatures on the exterior surface of the device. Other techniques may be implemented as well, including, but not limited to, larger heat wells, sinks or insulators, a metal connector cap and heavier copper content in the flex circuit or the handle **302** of the device.

Another advantage of a removable battery assembly **301** is realized when lithium-ion (Li) batteries are used. As previously stated, lithium batteries should not be charged in a parallel configuration of multiple cells. This is because, as the voltage increases in a particular cell, it begins to accept additional charge faster than the other lower-voltage cells. Therefore, each cell must be monitored so that a charge to that cell can be controlled individually. When a lithium battery is formed from a group of cells **701***a-n*, a multitude of wires extending from the exterior of the device to the batteries **701***a-n* is needed (at least one additional wire for each battery cell beyond the first). By having a removable battery assembly **301**, each battery cell **701***a-n* can, in one exemplary embodiment, have its own exposed set of contacts and, when the battery assembly **301** is not present inside the handle assembly **302**, each set of contacts can be coupled to a corresponding set of contacts in an external, non-sterile, battery-charging device. In another exemplary embodiment, each battery cell **701***a-n* can be electrically connected to the battery protection circuitry **702** to allow the battery protection circuitry **702** to control and regulate recharging of each cell **701***a-n*. The battery assembly **301** of the present invention is provided with circuitry to prevent use of the battery assembly **301** past an expected term-of-life. This term is not only dictated by the cells but is also dictated by the outer surfaces, including the battery casing or shell and the upper contact assembly. Such circuitry will be explained in further detail below and includes, for example, a use count, a recharge count, and an absolute time from manufacture count.

Turning now to FIG. **33**, at least one additional novel feature of the present invention is clearly illustrated. The battery assembly **301** shown in FIG. **33** shows a fully assembled battery assembly **301** that has been, for instance, ultrasonically welded so that the two shell halves **2802***a* and **2802***b*, as well as the potted multi-lead battery terminal assembly **2804**, provide a hermetic seal between the environment and the interior of the battery assembly **301**. The gap between the terminal assembly **2804** and the shell halves **2802***a* and **2802***b* is wide enough to allow for automated dispense of sealing materials such as light cure adhesives or epoxies. Although shown in several of the previous drawings, FIG. **33** illustrates an inventive catch **3300**, which is formed by an extended portion of the shell **2802** that is shaped by a generally longitudinal void **3302** directly under the catch **3300**, both being located at an upper portion of the exterior of the shell **2802**. The catch **3300** is shaped to mate with a receiver **3400** in a lower battery dock **3401** of the handle assembly **302**, which is shown in FIG. **34**.

FIG. **35** illustrates an underside of the handle assembly **302** and provides an improved view of the receiver **3400** and the battery dock **3401**. As is can be seen in FIG. **35**, the receiver **3400** extends from the battery dock **3401** (formed by a handle shell **3500**) and is shaped to mate with, i.e., fit within, the void **3302** of the battery assembly **301**. In addition, the receiver **3400** is in close proximity to a multi-lead handle terminal assembly **3502**, which includes a plurality of handle-connection pins **3504***a-n*. In the exemplary embodiment shown in FIG. **35**, each handle contact pin in the multi-lead handle terminal assembly **3502** is a spring-type contact pin that is capable of being compressed while exerting an amount of force in a direction opposite the compression force and, thereby, maintaining a positive electrical connection between the handle-connection pin **3504***a-n* and the object applying the force. In addition, the handle-connection pins **3504***a-n* of the multi-lead handle terminal assembly **3502** are spaced so that each of the handle-connection pins **3504***a-n* physically aligns with a respective one of the contact pads **2806***a-n* of the multi-lead battery terminal assembly **2804**.

To couple the inventive battery assembly **301** to the inventive handle assembly **302**, the catch **3300** is contacted with the receiver **3400**, as is shown in FIG. **36**, and the battery assembly **301** is rotated with respect to the handle assembly **302**, as is shown in the progression from FIG. **36** to FIG. **37**. Although not limited to the exemplary embodiments shown in the figures of the instant specification, the physical shapes of the catch **3300** and receiver **3400** shown in FIGS. **33-35** (particularly the rounded corners **3305** shown in FIG. **33**) cause the battery assembly **301** to align itself with the handle assembly **302** virtually regardless of the angle to which the battery assembly **301** approaches the receiver **3400**, as long as the catch **3300** and receiver **3400** are in physical contact with each other. With any rotation of the battery assembly **301** between the position shown in FIG. **36** and the position shown in FIG. **37**, the catch **3300**, or rather, the void **3302**, automatically seats upon the receiver **3400**. This means that a user in the sterile field can easily connect the battery assembly **301** to the handle assembly **302** and, especially, can do so without actually viewing the two parts during connection efforts.

In accordance with one exemplary embodiment of the present invention, the multi-lead handle terminal assembly **3502**, as shown in FIG. **35**, includes a gasket **3512** that surrounds the handle-connection pins **3504***a-n* and is sealed to a flex circuit board **3514** that supports the handle-connection pins **3504***a-n*. In one exemplary embodiment, the gasket **3512** is part of a rigid-flex circuit that includes the flex circuit board **3514**, a flex circuit or harness **3516** (to be connected to the TAG assembly **303**), and the handle-connection pins **3504***a-n*. A portion of the flex circuit board **3514** is made relatively rigid or stiffer as compared to the rest of the flex harness **3516**. When the gasket **3512** is compressed during connection of the battery assembly **301** to the handle assembly **302**, rigid portions of the flex circuit board **3514** adjacent the gasket **3512** support the gasket **3512** and allow the gasket **3512** to be compressed without substantial movement when the battery assembly **301** is coupled to the handle assembly **302**. When the multi-lead battery terminal assembly **2804** and the multi-lead handle terminal assembly **3502** are placed together, as shown in FIGS. **59** and **60**, a seal exists between an outer periphery **3312** of the multi-lead battery terminal assembly **2804** and the gasket **3512** of the multi-lead handle terminal assembly **3502**. The seal prevents moisture from penetrating the interior of the gasket **3512**, i.e., reaching the handle-connection pins **3504***a-n* of the multi-lead handle terminal assembly **3502** or the contacts pads **2806***a-n* of the multi-lead battery terminal assembly **2804**. This sealing method only requires that the portions of the contact pins that extend through the stiffener be insulated on the side opposite the gasket. Such a sealing method is also used on the TAG connector **5010** and on the handle **302** as described in further detail below. Such configuration allow for the production of a device where sealing all potential openings is not necessary, thereby resulting in a cost and complexity savings.

According to an exemplary embodiment of the present invention, the flex circuit board **3514** is made from two copper trace layers separated and insulated with polyimide. As provided above, portions of the flex circuit board **3514** can be made relatively stiffer. For example, certain portions of the flex circuit board **3514** may contain a stiffener, e.g., FR-4 stiffener, bonded to the flex circuit board **3514**. The portions of the flex circuit board **3514** with the stiffener provide a mechanical way of rigidly holding components within the disposable handle assembly **302**.

In accordance with another exemplary embodiment of the present invention, the two body halves **4503**, **4603** of the handle assembly **302** hold the rigid sections therebetween within the handle assembly **302** under close tolerances. Where the flex circuit board **3514** has a stiffener **10902** in a horizontal orientation, and the flex circuit board **3514** transitions to a vertical orientation, as shown in FIG. **108**, the flex circuit board **3514** can be damaged if not allowed to gradually transition. The rigid portions (e.g., **10902**) of the flex circuit board **3514** are desired to be at or within a slot or track **10804** in the body material. Therefore, to hold the rigid portions firmly on all sides, a portion **10806** of the flex circuit board **3514** is designed to peel away from the rigid portion **10902** before reaching the end of the flex circuit board **3514**. No adhesive is placed in this area. According to an exemplary embodiment of the present invention, on this battery side of the flex circuit board **3514**, i.e., the stiffened board from which the battery contact pins **2906***a-n* protrude, has a custom connector made from, for example, FR-4 material or molded plastic. This can be seen, for example, in FIG. **60**. The molded plastic can contain either insert molded metal contacts or the contacts can be inserted after molding and then potted for sealing purposes. The FR-4 or molded plastic is then bonded to the flex circuit board **3514** with an adhesive. In a molded configuration, the connector can be made to have rows of rigid material raised between the contacts or even a grid of material to protect the contact from mechanical damage.

As shown in FIG. **56** and explained in detail below, the rigid-flex circuit of the handle assembly **302** electrically couples the handle-connection pins **3504***a-n* to the handle assembly's TAG electrical connector **5602**.

Referring briefly back to FIG. **35**, the handle body **3500** of the handle assembly **302** is provided with an extended battery securing portion **3506**. The extended battery securing portion

3506 is on a side of the multi-lead handle terminal assembly 3502 opposite the receiver 3400. It is noted that the particular exemplary embodiment of the handle-securing portion shown in FIG. 35 includes a pair of voids 3508 and 3510, which are not necessary to complete the battery-handle securing process. Referring now to FIG. 38, an additional feature of the battery assembly 301 is shown. In this view, a pair of bosses 3802, 3804 can be seen on an exterior side of the battery assembly shell 2802. The bosses 3802, 3804 are spaced and positioned to mate with the voids 3508, 3510 in the extended battery securing portion 3506 of the handle body 3500. This mating position is illustrated in FIG. 37. Referring still to FIG. 38, it can be seen that each of the bosses 3802, 3804 are provided with a sloped upper portion 3816 and an opposing sharp-edge bottom portion 3818. The sloped upper portion 3816 allows the bosses 3802, 3804 to easily slip into the voids 3508, 3510 in the extended battery securing portion 3506 of the handle assembly 302 when the battery assembly 301 is being secured to the handle assembly 302. The sharp-edge bottom portions 3818 secure and allow the bosses 3802, 3804 to remain seated within the extended battery securing portion 3506 of the handle assembly 302.

The combination of the mating between the catch 3300 and receiver 3400 at one side of the battery assembly 301 and the mating between the bosses 3802, 3804 and the voids 3508, 3510, respectively, at the other side of the battery assembly 301 provides a solid and secure attachment of the battery assembly 301 to the handle assembly 302 (see also FIGS. 3 and 37). In an exemplary embodiment, the two bosses 3802, 3804 are spaced as far apart from each other as is practical. This spacing improves the strength and stability of the attachment between the battery assembly 301 and the handle assembly 302. This stability is further improved by the overlap between the disposable and the battery at faces 3520 and 3305, seen in FIGS. 35 and 33, respectively.

FIG. 38 also illustrates a release mechanism 3806 coupled to the exterior of the battery assembly shell 2802. The release mechanism 3806 is provided with peripheral edges 3808 that are secured by and slide within a pair of corresponding channels 3810, 3812 formed within the same exterior side of the battery assembly shell 2802 as the bosses 3802, 3804. The fit between the release mechanism 3806 and the battery casing 2802*a*, 2802*b* is loose so that water is able to flow between the mating parts for cleaning before sterilization. To assist in the cleanability of the release mechanism 3806, holes can be added; in the exemplary embodiment, two oval holes are present. Additionally, all edges of release mechanism 3806 are curved to limit the contacted surface area. A face of the release mechanism 3806 facing the battery casing has a concave cut down the center of it to further reduce the mated surface area. The release mechanism 3806 has a sloped nose region 3814 that is operable for moving toward and away from the bosses 3802 and 3804 and, in the particular embodiment shown in FIG. 38, extends between the bosses 3802 and 3804 when the release mechanism 3806 is slid in an upwardly direction. This nose 3814 also forces the battery latch down and out of the way during connection of the battery assembly 301. The release mechanism 3806 is made of a lubricious yet tough material that can supply low friction but also withstand the extended use of the battery assembly 301—a reusable portion of the device. Materials such as graphite and/or carbon-fiber reinforced PTFE are suitable, for example.

When the battery assembly 301 is securely coupled to the handle assembly 302, as is shown in FIG. 37, the release mechanism 3806 remains in a position within the channels 3810, 3812 that is furthest away from the handle assembly 302. When a user desires to remove the battery assembly 301 from the handle assembly 302, the release mechanism 3806 is slid within the channels 3810, 3812 in a direction toward the handle assembly 302. This sliding action causes the sloped nose region 3814 to enter the area between the battery assembly 301 and the lowermost portion of the extended battery securing portion 3506. As the sloped nose region 3814 moves forward, it forces the extended battery securing portion 3506 to ride up on the sloped nose region 3814 and flex away from the battery assembly 301. Stated differently, the extended battery securing portion 3506 bends away from the multi-lead handle terminal assembly 3502 and receiver 3400. To eliminate risk of inadvertently releasing the battery assembly 301 from the handle assembly 302 while the jaw is closed, the trigger 4606 is configured to cover or protect the battery release mechanism 3806. Therefore, with the trigger 4606 fully depressed, the battery release mechanism 3806 is fully covered, thereby preventing user actuation of the release mechanism 3806 to release the battery assembly 301.

Once the extended battery securing portion 3506 flexes to a certain degree, the bottom edges 3818 of the bosses 3802 and 3804 no longer engage with the voids 3508 and 3510 and the battery assembly 301 can easily be rotated from the orientation shown in FIG. 37 to that shown in FIG. 36 and, ultimately, separated from the handle assembly 302. The release mechanism 3806 is, of course, only one example of a mechanism that secures the battery assembly 301 to and releases the battery assembly 301 from the handle assembly 302. The release mechanism 3806 is advantageous in that it renders unintended detachment very unlikely. To release the battery assembly 301, an operator needs to move the release mechanism 3806 toward the handle while, at the same time, rotating the battery assembly 301 away from the handle assembly 302. These two oppositely-directed forces/actions are very unlikely to occur simultaneously unless they are performed intentionally. Application of these different forces also requires the user's hands to be in a position different than an in-use position during surgery. Such a configuration virtually ensures that accidental separation of the battery assembly 301 and handle assembly 302 does not occur.

The present invention also provides a significant advantage over prior art devices in the way the electrical connection between the multi-lead handle terminal assembly 3502 and the multi-lead battery terminal assembly 2804 is formed. More specifically, looking again to FIG. 33, it can be seen that, in the illustrated exemplary embodiment of the multi-lead battery terminal assembly 2804, sixteen contact pads 2806 are present—the contact pads 2806*a-d* forming a first row 3304, contact pads 2806*e-h* forming a second row 3306, contact pads 2806*i-l* forming a third row 3308, and contact pads 2806*m-p* forming a fourth row 3310.

Similarly, as is shown in FIGS. 34 and 35, the multi-lead handle terminal assembly 3502 includes a plurality of handle-connection pins 3504*a-n* (only twelve of the sixteen pins 3504*a-n* are shown in the view of FIG. 35). The handle contact pins are configured so that, when the battery assembly 301 is coupled to the handle assembly 302, each handle-connection pin 3504*a-n* is aligned with an individual one of the contact pads 2806. Therefore, the handle-connection pins 3504*a-n* are also disposed, in the particular embodiment shown in the drawings, in four rows 3404, 3406, 3408, and 3410.

When the battery assembly 301 is to be attached to the handle assembly 302, the catch 3300 is first placed in contact with the receiver 3400 and the battery assembly 301 is then rotated toward the extended battery securing portion 3506 until the bosses 3802, 3804, respectively, engage the voids 3508, 3510 in the extended battery securing portion 3506.

One significant result of the rotation is that the physical/electrical connection between the multi-lead handle terminal assembly **3502** and the multi-lead battery terminal assembly **2804** occurs sequentially, one row at a time, starting with battery row **3304** and handle row **3404**.

According to an exemplary embodiment of the present invention, the first battery row **3304** includes a grounding contact pad and the last battery row **3410** includes at least one power contact pad. Therefore, the first contact between the multi-lead battery terminal assembly **2804** and the multi-lead handle terminal assembly **3502** is a grounding connection and the last is a power connection. Installation of the battery assembly **301** will not cause a spark because the ground contact of the battery assembly **301** is a distance away from the last row **3410** of the multi-lead handle terminal assembly **3502** when the powered connection is made. As the battery assembly **301** is rotated into an attachment position (shown in FIG. **37**), each battery row **3304**, **3306**, **3308**, **3310** sequentially makes contact with each handle row **3404**, **3406**, **3408**, **3410**, respectively, but the power contact(s) is(are) only connected after a row having at least one grounding contact has been connected. In other words, as the battery assembly **301** is installed into the handle assembly **302**, the battery assembly **301** is advantageously grounded before any power contacts are brought into contact with any portion of the handle assembly **302**—a significant advantage over prior-art device power supply couples. In all known devices, the contacts supplying power (i.e., electric mains) are coupled simultaneous to other couplings, or randomly, depending on the approach orientation of the electric plug. This prior-art coupling leaves sparking or arcing as a persistent possibility. With the present invention, however, the possibility of sparking or arcing that is present in the prior art is entirely eliminated.

In addition, in accordance with one exemplary embodiment of the present invention, one or more pins in any of the first **3404**, the second **3406**, the third **3408**, or the last row **3410** of the handle-connection pins **3504***a-n* are coupled to a battery presence detection circuit **3104**. In particular, one of the contacts in the last row **3410** is used as a present pad. The battery presence detection circuit **3104**, after detecting the proper connection of the grounding pin(s) and the present pin of the multi-lead handle terminal assembly **3502** to the multi-lead battery terminal assembly **2804**, allows operation of the ultrasonic surgical assembly **300**. In the embodiment where the battery present detection pad(s) is/are only in the last row, i.e., furthest away from the receiver **3400**, the handle assembly **302** will not alter/change states until the battery assembly **301** is fully and securely installed, i.e., all contacts are properly connected. This advantageous feature prevents any improper operation of the overall assembly. Similarly, when disconnecting the battery assembly **301**, the last row **3410** is the first row disconnected from the handle-connection pins **3504***a-n*. Therefore, the device immediately responds to the absence of the battery assembly **301** from the handle assembly **302**.

In the exemplary embodiment, the battery protection circuit **702**, i.e., the fuel gauge, monitors the present pad and waits for it to be grounded before powering the microprocessor **1006** within the TAG assembly **303**. To do this, of course, the TAG assembly **303** must also be coupled to the handle assembly **302**. More particularly, the TAG assembly **303** must be electrically coupled to the handle assembly's TAG electrical connector **5602**. Once the TAG assembly **303** is coupled to the handle assembly's TAG electrical connector **5602** (see, e.g., FIGS. **36** and **37**) and the battery assembly **301** is properly coupled to the multi-lead handle terminal assembly **3502** (see, e.g., the configuration shown in FIG. **37**), communication between the battery assembly **301** and the TAG assembly **303** occurs. After such communication is established, the device is ready for use and the battery controller **703** can signal a "ready-for-use" state to the user, for example, by generating an indicative tone at the buzzer **802** within the handle assembly **302** and/or generating a visual indicator at the LEDs **906**.

In one exemplary embodiment for establishing this communication, the battery protection circuit **702** senses the presence of a proper connection between the battery assembly **301** and the handle assembly **302** by periodically pulsing a low-voltage signal to the present pad. The battery protection circuit **702** monitors the present pad for a connection to ground, which ground is provided by the handle assembly **302** once the battery assembly **301** is properly connected thereto. However, because the battery assembly **301** may be exposed to bodily fluids or submerged in a solution, for example, water during cleaning, it is advantageous for the battery assembly **301** not to sense a false ground condition as if the battery assembly **301** has been properly connected to the handle assembly **301** when the ground condition is only due to the fluid or solution electrically coupling the present pad to ground. More specifically, when the device is being disinfected and cleaned, the contacts are exposed to electrolytes having a finite resistance. In such a case where protection circuitry is not provided, the circuit that turns on the battery pack will activate the boards in the presence of such electrolytes. Large currents are able to flow between the voltage-enabled pins to the battery ground. This current flow establishes a motion of metal ions that will cause pitting or electrodeposition in the contacts, which is undesirable because a brief exposure to electrolyte badly corrodes the contacts, rendering them unusable. Another undesirable situation could exist during battery installation. When a proper battery-handle contact closure is achieved, the resistance of the conductive lines sensed by the microcontroller is very low. But if fluid is present, a larger resistance exists. The microcontroller is so sensitive that such a large resistance could activate the device.

For these reasons, embodiments of the present invention provide a comparator, for example through software, that monitors the impedance between the present pad and ground (i.e., the GND line in the TAG assembly shown in FIG. **9**). The comparator compares the impedance of a coupling between the present pad and ground to the reference impedance so that only when the impedance is less than a threshold impedance, i.e., less than that of a solution, will the battery assembly **301** operate. More specifically, the comparator circuit compares a reference voltage against the voltage generated both when the battery present contact is exposed to either a short-to-ground or to an electrolyte of finite resistance mentioned above. If the resistance is such that the voltage generated matches the reference voltage, then the battery will turn on. The reference voltage is adjusted so that fluids present during battery-handle contact will not allow the battery pack to turn on. The comparator circuit is configured with a strong hysteresis to prevent inadvertent self turn-off due to noise and the sensitive nature of this circuit.

The illustrated design of the multi-lead handle terminal assembly **3502** provides even further advantages over the prior art. In particular, the inventive handle-connection pins **3504***a-n*, shown in the enlarged partial perspective view of FIG. **39**, provide a physical connection along with a lateral displacement that ensures removal of any foreign substances from the contact region where the handle-connection pins **3504***a-n* of the multi-lead handle terminal assembly **3502** meet the contact pads **2806**_a-n_ of the multi-lead battery terminal assembly **2804**. Specifically, FIG. **39** shows the first handle-connection pin **3504**_a_ in its at-rest, non-contact state. That is, the handle-connection pin **3504**_a_ has a spring force that places and retains it in the natural resting shape shown in FIG. **39**. However, when the multi-lead battery terminal assembly **2804** is fully mated with the multi-lead handle terminal assembly **3502**, the handle-connection pins **3504**_a-n_ compress. This compressed state is shown, for example, by handle-connection pins **3504**_b_ and **3504**_f_ in FIG. **39**.

The compression placed on the handle-connection pin **3504**_a-n_ by the contact pad **2806** not only provides positive pressure to retain the electrical connection, but also causes the connecting surface of each handle-connection pin **3504**_a-n_ to move a distance D with respect to the longitudinal extent of the pin **3504**. This distance D is illustrated in FIG. **39** by a first vertical line **3901** showing where an apex of a connecting surface of a first handle-connection pin **3504**_e_ exists when the pin **3504**_e_ is in its uncompressed state. A second vertical line **3902** shows where the apex of the connecting surface of the neighboring second handle-connection pin **3504**_f_ exists when the pin **3504**_f_ is compressed. The distance between the two lines defines a longitudinal distance D that the connecting surface of each pin **3504**_a-n_ translates when compressed. This movement is initiated when the handle-connection pin **3504**_a-n_ and the respective contact pad **2806** first make contact and continues until the battery assembly **301** is fully seated between the receiver **3400** and the extended battery securing portion **3506**, as shown in the cutaway perspective view FIG. **40**. The translation movement of the handle-connection pins **3504**_a-n_ produces a swiping motion that effectively wipes the contact pad **2806** clean, thus improving electrical connection therebetween. This wiping effect can prove highly advantageous when, for instance, a battery needs to be replaced in an operating environment and contaminant material, such as blood, comes into contact with the contact pads **2806** or when the pads are corroded from repeated use or due to exposure to cleaning agents.

The view of FIG. **35** shows yet another advantageous feature of the present invention. Therein, it can be seen that the multi-lead handle terminal assembly **3502** features flanged sides **3520** that protect the handle-connection pins **3504**_a-n_ of the handle assembly **302** from the left and right sides because they extend in a direction away from the plane of the pins **3504**_a-n_. The receiver **3400** also extends in the direction away from the plane of the pins **3504**_a-n_ to protect the pins from the rear. Finally, the battery securing portion **3506** significantly extends in the direction away from the plane of the pins **3504**_a-n_ to protect the pins from the front. Users know from the ergonomic shape of the battery pack **301** and the handle **302** that the battery pack **301** is configured to attach to the handle **302** in a particular plane as illustrated clearly in FIGS. **36** and **37**. Knowing this, the four extending sides of the lower battery dock **3401** are sized to prevent any injury to the pins **3504**_a-n_ when the user attempts to insert the battery **301** into the dock **3401**. To illustrate this more specifically, two planes are defined, one for each of the battery **301** and the handle **302**. These planes are parallel to the page including FIG. **3** and are coplanar when the battery **301** is installed in the handle **302**. The plane relating to the handle **302** is referred to as a distal-to-proximal central handle plane and vertically bisects the handle like the page of the drawing of FIG. **3**. Similarly, the plane relating to the battery **301** is referred to as the distal-to-proximal central battery plane and vertically bisects the handle like the page of the drawing of FIG. **3**. With these planes defined, the pin safety feature is explained.

The receiver **3400** and the battery securing portion **3506** are shaped with a length that does not permit the front top corner **3008** of the battery from touching the pins **3504**_a-n_ when the distal-to-proximal central battery plane is within approximately 30 degrees of the distal-to-proximal central handle plane. Likewise, the receiver **3400** and the battery securing portion **3506** are shaped with a length that does not permit the rear top corner, i.e., the catch **3300**, of the battery **301** from touching the pins **3504**_a-n_ when the distal-to-proximal central battery plane is within approximately 30 degrees of the distal-to-proximal central handle plane. This configuration ensures safe and easy connection of the battery **301** to the handle **302**.

A further advantage of the present invention is that the entire battery assembly **301** can be sterilized. If there is a need for replacement during a medical procedure, the battery assembly **301** can be easily replaced with a new sterile battery assembly **301**. The gas-tight construction of the battery assembly **301** allows it to be sterilized, for example, using low-temperature vapor phase Hydrogen Peroxide (H_2O_2) as performed by the sterilization devices manufactured by the Steris Corporation and referred to under the trade name V-PRO or manufactured by Advanced Sterilization Products (ASP), division of Ethicon, Inc., a Johnson & Johnson company, and referred to under the trade name STERRAD®. Because the Lithium cells of the battery assembly **301** are damaged when heated above 60° C., non-heating sterilization commonly used in hospitals today makes the battery assembly **301** easily re-used in surgical environments.

a. Battery Pressure Valve

The battery assembly **301** of the present invention features yet another inventive feature. As shown in FIG. **37**, the battery assembly **301** includes an exemplary embodiment of a pressure valve **3702** that, as will be explained below, prevents the influence of external atmospheric pressure—both positive and negative—on the battery assembly's internal pressure, while providing for emergency pressure relief for excess internal pressure, e.g., >30 psi. This valve **3702**, advantageously, has a large enough opening to vent any internally accumulating gases quickly. Also advantageously, the inventive valve **3702** does not instantaneously open and close with small changes in pressure, as do some prior art venting devices. Instead, the opening and closing events of the valve **3702** have several defined stages. In an exemplary configuration of the valve **3702**, during the first stage (<30 psi), the valve **3702** remains sealed, as shown in FIGS. **41** and **42**, and does not allow gas flow into or out of the battery compartment. This exemplary embodiment can be referred to as a so-called poppet valve. In stage 2, once the battery assembly's internal pressure has increased just enough to counter the force of a spring **4102** holding an O-ring **4104** surrounding a poppet **4106** against a valve seat **4202**, shown in the cutaway view of FIG. **42**, fluid/gas will begin to escape between the O-ring **4104** and the seat **4202**. In stage 3, the internal pressure has pushed the valve **3702** open enough to allow a significant amount of fluid/gas to pass the seal **4104**, **4202**. At this point, and up to stage 4, internal pressure has forced the valve completely open, i.e., the O-ring **4104** has moved completely off of the seat **4202**. Additional pressure has diminished effect on the flow because the valve cannot open further.

In stage 5, pressure on the valve **3702** begins to decrease and the poppet **4106** starts to shut. As the poppet **4106** retracts, it follows the same sequence as occurred during opening through hysteresis (i.e., retardation of an effect when forces acting upon a body are changed, dictating that a lag in closing occurs). As a result, when the poppet **4106** begins its return, it lags in position relative to the curve of FIG. **44** traversed when the poppet **4106** was opening. At stage 6, the O-ring **4104** just touches the seat **4202**. The valve **3702** does not seal at this point, as there is no force pressing the O-ring **4104** into the seat **4202**. In step **7**, the force of the spring **4102** compresses the O-ring **4104** with sufficient force to seal the valve shut. The valve **3702** can now return to stage 1, shown in FIGS. **41** and **42**. The valve **3702** is re-sealable multiple times as the sealing surface is tapered to minimize stiction.

For ease of testing the valve **3702**, the poppet **4106** is formed with a tear-off handle **4108**. The handle **4108** is operable to move the poppet **4106** (manually or automatically) to provide access within the battery assembly **301** for the purpose of testing the ultrasonic weld or the bonded shell halves **2802***a*, **2802***b* for leaks. For example, a user or leak-testing fixture can grasp the handle **4108** and move the poppet **4106** out and back within the valve dock **4204**, which is shown in FIGS. **41** and **42** as located in one half of the outer shell **2802***a* or **2802***b* of the battery assembly **301**. Alternatively, the handle **4108** may be used to provide access to the interior of the battery assembly **301** to back fill the battery compartment with inert gas or trace gas, e.g., helium, or even to pull a vacuum within the interior of the battery assembly **301**. When testing is finished, the user, for example, the manufacturer, can tear off or otherwise remove the handle **4108** to prevent further user-controlled poppet **4106** movement. Removal of the handle **4108** is made easier with a narrowing **4110** formed at the base of the handle **4108**. For example, the narrowing **4110**, shown in FIGS. **41** to **43**, includes sharp corners to provide a consistent and smooth breaking point.

In this exemplary embodiment, the handle **4108** has an arrowhead and tab configuration. As shown in FIGS. **41** to **43**, the poppet **4106** includes clocking tabs **4112** on at least one side of the poppet **4106** to maintain the arrowhead in a desired orientation, e.g., horizontal to the ground when the ultrasonic surgical assembly **300** is in use, to facilitate machine or automated access to the inside of the battery assembly **301** for leak-testing operations. The arrowhead includes a gentle taper, which assists in the installation of the O-ring **4104**—the O-ring **4104** is able to slide easily over the tapered arrowhead without breaking off the arrowhead tab.

In an exemplary embodiment, the O-ring **4104** is made of a STERRAD® compatible material having a durometer of between approximately 40 and approximately 60 (e.g., VITON®) as such materials seal more reliably on molded parts having irregular surface finishes.

In another exemplary embodiment, the poppet **4106** is formed from a different material than the battery shell **2802** to prevent sympathetic welding during ultrasonic welding of the battery shell halves **2802***a*, **2802***b*.

As shown in FIG. **37**, the valve **3702** is advantageously disposed at the very bottom of the battery assembly **301**. In this exemplary configuration, the valve **3702** remains outside the working area of the hand grip, i.e., the battery outer shell **2802**, to prevent interference with the user's handling of the ultrasonic surgical assembly **300**. Further, this positioning of the valve **3702** increases safety by preventing injury to the user's hand should venting occur through the valve **3702**. At the same time, the user's hand does not block the valve **3702** from venting.

Also advantageously, the valve **3702** is easy to clean. The smooth outer surface of the poppet **4106** allows direct access to the O-ring **4104** seal area. Likewise, the blended smooth features of the poppet **4106** create no hidden areas in which dirt or grime could become trapped.

The battery assembly **301** of the present invention may include inventive features alternative to the valve **3702** described above. In one exemplary embodiment, the battery assembly **301** may include a non-illustrated burst plug installed within a battery access hole or relief port in the bottom side of one of the shell halves **2802***a*, **2802***b*. In this exemplary configuration, the burst plug is formed from a molded flexible material and is able to be press fit into the access hole. Alternatively, the burst plug may be molded to the inside of the battery access hole. As installed, the burst plug is flush with the outer surface of the battery shell **2802** to prevent dirt or grime collection or interference with the user's hand. The burst plug provides emergency pressure relief for excess internal pressure, e.g., >30 psi. Such excess internal pressure forces the burst plug to exit the battery relief port and vent any internally accumulating gases quickly. In this exemplary embodiment, a T-tail on the inside end of the molded burst plug prevents the burst plug from detaching from the battery assembly **301** and becoming lost or potentially falling into a patient during a surgical procedure. Further, where the burst plug is retained to the battery with the T-tail, the dangling burst plug becomes an advantageous visual indicator to a user that adverse conditions in the battery assembly **301** have occurred.

In another exemplary embodiment, the battery assembly **301** may include a burst disk installed over the battery access hole or relief port in the bottom side of one of the shell halves **2802***a*, **2802***b*. In this exemplary embodiment, the burst disk may comprise a foil tape disk placed over the battery relief port, or a disk of material with known shear characteristics. The disk can be ultrasonically welded, bonded, or otherwise sealed in place over the battery relief port to serve as a blow-off relief valve. Advantageously, the relief port may include an array or grid of many small openings. Such a configuration prevents inadvertent rupture of the disk from external mechanical measures.

In yet another exemplary embodiment, one of the shell halves **2802***a* or **2802***b* of the battery assembly outer shell **2802** may include a molded blow-out or relief area where the molded material of the outer shell half **2802***a* or **2802***b* is particularly thinner than the rest of the outer shell **2802**. The relief area of the outer shell **2801** is thus designed to fail when a pre-defined, undesirable pressure is reached within the interior of the battery assembly **301**. Further, a pattern, e.g., a flower-petal pattern, may be scored onto the molded surface of one of the shell halves **2802***a* or **2802***b* to provide additional stress concentrators as well as serve as a hinge to prevent petal loss after pressure relief occurs, and thus prevent pieces of the ruptured molded material of the shell **2802** from detaching from the battery assembly **301** and possibly becoming lost or falling into a patient.

In again another exemplary embodiment, the battery assembly **301** may include a pressure relief configuration akin to a turkey popper valve. Rather than having a self-reseating valve, as described above with respect to the poppet valve **3702**, the turkey popper valve is retained in an actuated position after relief of excess internal pressure within the battery assembly **301**. This provides a visual indicator to the user that adverse conditions existed within the battery. In this configuration, the turkey popper valve may be selectively reseated to allow for further use of the battery assembly **301**.

b. Intelligent Battery

In additional exemplary embodiments of the present invention, an intelligent or smart battery is used to power the surgical ultrasonic surgical cautery assembly **300**. However, the smart battery is not limited to the ultrasonic surgical cautery assembly **300** and, as will be explained, can be used in a variety of devices, which may or may not have power requirements (i.e., current and voltage) that vary from one another. The smart battery, in accordance with an exemplary embodiment of the present invention, is advantageously able to identify the particular device to which it is electrically coupled. It does this through encrypted or unencrypted identification methods. For instance, a battery assembly **301** shown in FIG. **57** can have a connection portion, such as portion **5702**. The handle assembly **302** can also be provided with a device identifier **5704** communicatively coupled to the multi-lead handle terminal assembly **3502** and operable to communicate at least one piece of information about the handle assembly **302**. This information can pertain to the number of times the handle assembly **302** has been used, the number of times a TAG assembly **303** (presently connected to the handle assembly **302**) has been used, the number of times a waveguide assembly **304** (presently connected to the handle assembly **302**) has been used, the type of waveguide assembly **304** that is presently connected to the handle assembly **302**, the type or identity of the TAG assembly **303** that is presently connected to the handle assembly **302**, and/or many other characteristics. When the smart battery assembly **301** is inserted in the handle assembly **302**, the connection portion **5702** within the smart battery assembly **301** makes communicating contact with the device identifier **5704** of the handle assembly **302**. The handle assembly **302**, through hardware, software, or a combination thereof, is able to transmit information to the smart battery assembly **301** (whether by self-initiation or in response to a request from the battery assembly **301**). This communicated identifier is received by the connection portion **5702** of the smart battery assembly **301**. In one exemplary embodiment, once the smart battery assembly **301** receives the information, the communication portion **5702** is operable to control the output of the battery assembly **301** to comply with the device's specific power requirements.

In an exemplary embodiment, the communication portion **5702** includes a processor, such as processor **1118**, and a memory, which may be separate or a single component. The processor **1118**, in combination with the memory, is able to provide intelligent power management for the handheld ultrasonic surgical cautery assembly **300**. This embodiment is particularly advantageous because an ultrasonic device, such as handheld ultrasonic surgical cautery assembly **300**, has a power requirement (frequency, current, and voltage) that may be unique to the handheld ultrasonic surgical cautery assembly **300**. In fact, handheld ultrasonic surgical cautery assembly **300** may have a particular power requirement or limitation for one dimension or type of waveguide **1502** and a second different power requirement for a second type of waveguide having a different dimension, shape, and/or configuration.

A smart battery **301** according to the invention, therefore, allows a single battery assembly to be used amongst several surgical devices. Because the smart battery **301** is able to identify to which device it is attached and is able to alter its output accordingly, the operators of various different surgical devices utilizing the smart battery **301** no longer need be concerned about which power source they are attempting to install within the electronic device being used. This is particularly advantageous in an operating environment where a battery assembly needs to be replaced or interchanged with another surgical device in the middle of a complex surgical procedure.

In a further exemplary embodiment, the smart battery **301** stores in a memory **5706** a record of each time a particular device is used. This record can be useful for assessing the end of a device's useful or permitted life. For instance, once a device is used 20 times, all such batteries **301** connected to the device will refuse to supply power thereto—because the device is defined as a "no longer reliable" surgical instrument. Reliability is determined based on a number of factors. One factor can be wear, which can be estimated in a number of ways including the number of times the device has been used or activated. After a certain number of uses, the parts of the device can become worn and tolerances between parts exceeded. For instance, the smart battery **301** can sense the number of button pushes received by the handle assembly **302** and can determine when a maximum number of button pushes has been met or exceeded. The smart battery **301** can also monitor an impedance of the button mechanism which can change, for instance, if the handle gets contaminated, for example, with saline.

This wear can lead to an unacceptable failure during a procedure. In some exemplary embodiments, the smart battery **301** can recognize which parts are combined together in a device and even how many uses each part has experienced. For instance, looking at FIG. **57**, if the battery assembly **301** is a smart battery according to the invention, it can identify both the handle assembly **302**, the ultrasonic-cutting-blade-and-waveguide assembly **304**, as well as the particular TAG assembly **303**, well before the user attempts use of the composite device. The memory **5706** within the smart battery **301** can, for example, record each time the TAG assembly **303** is operated, and how, when, and for how long it is operated. If each TAG assembly **303** has an individual identifier, the smart battery **301** can keep track of each TAG assembly's use and refuse to supply power to that TAG assembly **303** once the handle assembly **302** or the TAG assembly **303** exceeds its maximum number of uses. The TAG assembly **303**, the handle assembly **302**, the ultrasonic-cutting-blade-and-waveguide assembly **304**, or other components can include a memory chip that records this information as well. In this way, any number of smart batteries **301** can be used with any number of TAG assemblies, staplers, vessel sealers, etc. and still be able to determine the total number of uses, or the total time of use (through use of the clock **330**), or the total number of actuations, etc. of each TAG assembly, each stapler, each vessel sealer, etc. or charge or discharge cycles.

When counting uses of the TAG assembly **303**, in order to intelligently terminate the life of the TAG assembly **303**, it becomes important to be able to accurately distinguish between completion of an actual use of the TAG assembly **303** in a surgical procedure and a momentary lapse in actuation of the TAG assembly **303** due to, for example, a battery change or a temporary delay in the surgical procedure. Therefore, as an alternative to simply counting the number of activations of the TAG assembly **303**, a real-time clock (RTC) circuit can be implemented to keep track of the amount of time the TAG assembly **303** actually is shut down. From the length of time measured, it can be determined through appropriate logic if the shutdown was significant enough to be considered the end of one actual use or if the shutdown was too short in time to be considered the end of one use. Thus, in some applications, this method may be a more accurate determination of the useful life of the TAG assembly **303** than a simple "activations-based" algorithm, which for example, may provide that ten "activations" occur in a single surgical procedure and, therefore, ten activations should indicate that the counter is incremented by one. Generally, this type and system of internal clocking will prevent misuse of the device that is designed to deceive a simple "activations-based" algorithm and will prevent incorrect logging of a complete use in instances when there was only a simple de-mating of the TAG assembly **303** or the battery **301** that was required for legitimate reasons.

Although the battery and TAG assemblies of the device are reusable, it is desirable to set a finite number of uses of the device. This could be necessary since the device is subjected to harsh conditions during cleaning and sterilization. More specifically, the battery pack is configured to be sterilized. Regardless of the material employed for the outer surfaces, there is a limited expected life for the actual materials used. This life is determined by various characteristics which could include, for example, the amount of times the pack has actually been sterilized, the time from which the pack was manufactured, and the number of times the pack has been recharged, to name a few. Also, the life of the battery cells themselves is limited. Software of the invention incorporates inventive algorithms that verify the number of uses in both the TAG and battery assemblies and disables the device when this number of uses has been reached or exceeded. Analysis of the battery pack exterior in each of the possible sterilizing methods can be performed. Based on the harshest sterilization procedure, a maximum number of permitted sterilizations can be defined and that number can be stored in a memory of the battery assembly **301**. If it is assumed that a charger is non-sterile and that the battery pack **301** is to be used after it is charged, then the charge count can be defined as being equal to the number of sterilizations encountered by that particular pack.

It is also desirable to permanently disable the hardware in the battery pack to minimize or eliminate safety concerns due to continuous drain in from the battery cells after the pack has been disabled by software. A situation can exist where the battery's internal hardware is incapable of disabling the battery under certain low voltage conditions. In such a situation, in an exemplary embodiment, the charger can be used to "kill" the battery. Due to the fact that the battery microcontroller is OFF while the battery is in its charger, a non-volatile, SMBus-based EEPROM can be used to exchange information between the battery microcontroller and the charger. Thus, a serial EEPROM can be used to store information that can be written and read even when the battery microcontroller is OFF, which is very beneficial when trying to exchange information with the charger or other peripheral devices. This exemplary EEPROM can be configured to contain enough memory registers to store at least (a) a use-count limit at which point the battery should be disabled (Battery Use Count), (b) the number of procedures the battery has undergone (Battery Procedure Count), and/or (c) a number of charges the battery has undergone (Charge Count), to name a few. Some of the information stored in the EEPROM, such as the Use Count Register and Charge Count Register are stored in write-protected sections of the EEPROM to prevent users from altering the information. In an exemplary embodiment, the use and counters are stored with corresponding bit-inverted minor registers to detect data corruption.

Any residual voltage in the SMBus lines could damage the microcontroller and corrupt the SMBus signal. Therefore, to ensure that the SMBus lines of the battery controller **703** do not carry a voltage while the microcontroller is OFF, relays are provided between the external SMBus lines and the battery microcontroller board.

During charging of the battery **301**, an "end-of-charge" condition of the battery **301** is determined when, for example, the current flowing into the battery falls below a given threshold in a tapering manner when employing a constant-current/constant-voltage charging scheme. To accurately detect this "end-of-charge" condition, the battery microcontroller and buck boards are powered down and turned OFF during charging of the battery to reduce any current drain that may be caused by the boards and that may interfere with the tapering current detection. Additionally, the microcontroller and buck boards are powered down during charging to prevent any resulting corruption of the SMBus signal.

With regard to the charger, it is desirable to prevent insertion of the smart battery **301** into the charger in any way other than the correct insertion position. Accordingly, as shown in FIG. **28**, for example, the exterior of the battery **301** is provided with charger-holding features **2810**. A cup for holding the battery **301** securely in the charger is configured with a contour-matching taper geometry to prevent the accidental insertion of the battery pack **301** in any way other than the correct (intended) way. It is further contemplated that the presence of the battery assembly **301** may be detectable by the charger itself. For example, the charger may be configured to detect the presence of the SMBus transmission from the battery protection circuit, as well as resistors that are located in the protection board. In such case, the charger would be enabled to control the voltage that is exposed at the charger's pins until the battery assembly **301** is correctly seated or in place at the charger. This is because an exposed voltage at the charger's pins would present a hazard and a risk that an electrical short could occur across the pins and cause the charger to inadvertently begin charging.

In some exemplary embodiments, the smart battery **301** can communicate to the user through audio and/or visual feedback. For example, the smart battery **301** can cause the LEDs **906** to light in a pre-set way. In such a case, even though the microcontroller **1006** in the generator **904** controls the LEDs **906**, the microcontroller **1006** receives instructions to be carried out directly from the smart battery **301**.

In yet a further exemplary embodiment, the microcontroller **1006** in the generator **904**, when not in use for a predetermined period of time, goes into a sleep mode. Advantageously, when in the sleep mode, the clock speed of the microcontroller **1006** is reduced, cutting the current drain significantly. Some current continues to be consumed because the processor continues pinging waiting to sense an input. Advantageously, when the microcontroller **1006** is in this power-saving sleep mode, the microcontroller **1106** and the battery controller **703** can directly control the LEDs **906**. For example, a decoder circuit could be built into the generator board **5460** and connected to the communication lines such that the LEDs **906** can be controlled independently by the battery microcontroller **1106** while the TAG microcontroller is "OFF" or in a "sleep mode." This is a power-saving feature that eliminates the need for waking up the microcontroller **1006**. Power is conserved by allowing the generator to be turned off while still being able to actively control the user-interface indicators.

Another exemplary embodiment slows down one or more of the microcontrollers to conserve power when not in use. For example, the clock frequencies of both microcontrollers can be reduced to save power. To maintain synchronized operation, the microcontrollers coordinate the changing of their respective clock frequencies to occur at about the same time, both the reduction and, then, the subsequent increase in frequency when full speed operation is required. For example, when entering the idle mode, the clock frequencies are decreased and, when exiting the idle mode, the frequencies are increased.

In an additional exemplary embodiment, the smart battery **301** is able to determine the amount of usable power left within its cells **701** and is programmed to only operate the surgical device to which it is attached if it determines there is enough battery power remaining to predictably operate the device throughout the anticipated procedure. For example, the smart battery **301** is able to remain in a non-operational state if there is not enough power within the cells **701** to operate the surgical device for 20 seconds. According to one exemplary embodiment, the smart battery **301** determines the amount of power remaining within the cells **701** at the end of its most recent preceding function, e.g., a surgical cutting. In this embodiment, therefore, the battery assembly **301** would not allow a subsequent function to be carried out if, for example, during that procedure, it determines that the cells **701** have insufficient power. Alternatively, if the smart battery **301** determines that there is sufficient power for a subsequent procedure and goes below that threshold during the procedure, it would not interrupt the ongoing procedure and, instead, will allow it to finish and thereafter prevent additional procedures from occurring.

The following explains an advantage of the invention with regard to maximizing use of the device with the smart battery **301** of the invention. In this example, a set of different devices have different ultrasonic waveguides. By definition, each of the waveguides could have a respective maximum allowable power limit where exceeding that power limit overstresses the waveguide and eventually causes it to fracture. One waveguide from the set of waveguides will naturally have the smallest maximum power tolerance. Because prior-art batteries lack intelligent battery power management, the output of prior-art batteries must be limited by a value of the smallest maximum allowable power input for the smallest/thinnest/most-frail waveguide in the set that is envisioned to be used with the device/battery. This would be true even though larger, thicker waveguides could later be attached to that handle and, by definition, allow a greater force to be applied. This limitation is also true for maximum battery power. For example, if one battery is designed to be used in multiple devices, its maximum output power will be limited to the lowest maximum power rating of any of the devices in which it is to be used. With such a configuration, one or more devices or device configurations would not be able to maximize use of the battery because the battery does not know the particular device's specific limits.

In contrast thereto, exemplary embodiments of the present invention utilizing the smart battery **301** are able to intelligently circumvent the above-mentioned prior art ultrasonic device limitations. The smart battery **301** can produce one output for one device or a particular device configuration and the same battery assembly **301** can later produce a different output for a second device or device configuration. This universal smart battery surgical system lends itself well to the modern operating room where space and time are at a premium. By having a single smart battery pack operate many different devices, the nurses can easily manage the storage, retrieval, and inventory of these packs. Advantageously, the smart battery system according to the invention requires only one type of charging station, thus increasing ease and efficiency of use and decreasing cost of surgical room charging equipment.

In addition, other surgical devices, such as an electric stapler, may have a completely different power requirement than that of the ultrasonic surgical cautery assembly **300**. With the present invention, a single smart battery **301** can be used with any one of an entire series of surgical devices and can be made to tailor its own power output to the particular device in which it is installed. In one exemplary embodiment, this power tailoring is performed by controlling the duty cycle of a switched mode power supply, such as buck, buck-boost, boost, or other configuration, integral with or otherwise coupled to and controlled by the smart battery **301**. In other exemplary embodiments, the smart battery **301** can dynamically change its power output during device operation. For instance, in vessel sealing devices, power management is very important. In these devices, large constant current values are needed. The total power output needs to be adjusted dynamically because, as the tissue is sealed, its impedance changes. Embodiments of the present invention provide the smart battery **301** with a variable maximum current limit. The current limit can vary from one application (or device) to another, based on the requirements of the application or device.

XII. Handle Assembly—Mechanical

FIG. **45** illustrates an exemplary embodiment of a left-hand side of the handle portion **302** with the left shell half removed. The handle assembly **302** has four basic functions: (1) couple the battery assembly **301** to the multi-lead handle terminal assembly **3502**; (2) couple the TAG assembly **303** to a TAG attachment dock **4502**; (3) couple the ultrasonic-cutting-blade-and-waveguide assembly **304** to a waveguide attachment dock **4504**; and (4) provide the triggering mechanics **4506** to operate the three components (battery assembly **301**, TAG assembly **303**, and ultrasonic-cutting-blade-and-waveguide assembly **304**).

a. TAG Attachment Dock

The TAG attachment dock **4502** is exposed to the environment and shaped to interchangeably secure the TAG assembly **303** to the handle assembly **302**. The waveguide attachment dock **4504** is shaped to align a proximal end of the waveguide **1502** to the transducer **902**. When the transducer **902** is docked in the TAG attachment dock **4502** and the waveguide assembly **304** is docked in the waveguide attachment dock **4504**, and the transducer **902** and waveguide **1502** are attached together, the waveguide **1502** and the transducer **902** are held at the handle assembly **302** in a freely rotatable manner.

As can be seen in FIGS. **45** and **46**, the handle assembly **302** includes two clamshell-connecting body halves, the right half **4503** being shown in FIG. **45** and the left half being shown in FIG. **46**. The two halves **4503**, **4603** form at least a portion of the waveguide attachment dock **4504**, which can be considered as being exposed to the environment when a waveguide rotation spindle **3704** is not present. A first couple **4602** is operable to selectively removably secure the ultrasonic waveguide assembly **304** to the handle assembly **302**. In the exemplary embodiment shown, the waveguide rotation spindle **3704** has an intermediate annular groove **4610** shaped to receive an annular boss **4605**. When the two halves **4503**, **4603** are connected, the groove **4610** and boss **4605** form a longitudinal connection of the waveguide assembly **304** that is free to rotate. In an exemplary embodiment, the ultrasonic-cutting-blade-and-waveguide assembly **304** is not user-removable from the handle assembly **302**.

The TAG attachment dock **4502** sits opposite the waveguide attachment dock **4504**. The TAG attachment dock **4502** is exposed to the environment and has a second couple **4604** operable to removably secure the ultrasonic transducer **902** to the ultrasonic waveguide **1502** when the ultrasonic waveguide assembly **304** is coupled to the waveguide attachment dock **4504**. The couples **4602** and **4604** can simply be aligned passageways or any other structure that place the waveguide **1502** into axial alignment with the transducer **902**. Of course, the couples **4602** and **4604** can provide more structure, such as threads, that actually hold the waveguide **1502** and/or transducer **902** to the handle or to one another. Some examples of the couple **4604** include a rail, a dovetail, a T-slot, at least one pin, more than one pin, and an undercut slot.

b. Controls

Looking now to FIG. **46**, a trigger **4606** and a button **4608** are shown as components of the handle assembly **302**. The trigger **4606** activates the end effector **118**, which has a cooperative association with the blade portion **116** of the waveguide **114** to enable various kinds of contact between the end effector **118** and blade portion **116** with tissue and/or other substances. As shown in FIG. **1**, the end effector **118** is usually a pivoting jaw (see also, e.g., FIG. **73** et seq.) that acts to grasp or clamp onto tissue disposed between the jaw and the blade **116**. In an exemplary embodiment, an audible feedback is provided in the trigger that clicks when the trigger is fully depressed. The noise can be generated by a thin metal part that the trigger snaps over while closing. This feature adds an audible component to user feedback that informs the user that the jaw is fully compressed against the waveguide and that sufficient clamping pressure is being applied to accomplish vessel sealing.

The button **4608**, when depressed, places the ultrasonic surgical assembly **300** into an ultrasonic operating mode, which causes ultrasonic motion at the waveguide **1502**. In a first exemplary embodiment, depression of the button **4608** causes electrical contacts within a switch **4702**, shown in FIG. **47**, to close, thereby completing a circuit between the battery assembly **301** and the TAG assembly **303** so that electrical power is applied to the transducer **902**. In another exemplary embodiment, depression of the button **4608** closes electrical contacts to the battery assembly **301**. Of course, the description of closing electrical contacts in a circuit is, here, merely an exemplary general description of switch operation. There are many alternative embodiments that can include opening contacts or processor-controlled power delivery that receives information from the switch **4702** and directs a corresponding circuit reaction based on the information.

FIG. **47** shows the switch **4702** from a left-side elevational view and FIG. **48** provides a cutaway perspective view of the interior of the right side of the handle body, revealing different detail of the switch **4800**. In a first exemplary embodiment, the switch **4800** is provided with a plurality of contacts **4804***a-n*. Depression of a plunger **4802** of the switch **4702** activates the switch and initiates a switch state change and a corresponding change of position or contact between two or more of the plurality of contacts **4804***a-n*. If a circuit is connected through the switch **4702**, i.e., the switch **4702** controls power delivery to the transducer **902**, the state change will either complete or break the circuit, depending on the operation mode of the switch **4702**.

FIG. **49** shows an exemplary embodiment of the switch **4702** that provides two switching stages. The switch **4702** includes two sub-switches **4902** and **4904**. The sub-switches **4902** and **4904** advantageously provide two levels of switching within a single button **4802**. When the user depresses the plunger **4802** inward to a first extent, the first sub-switch **4902** is activated, thereby providing a first switch output on the contacts **4804***a-n* (not shown in this view). When the plunger **4802** is depressed further inward to a second extent, the second sub-switch **4904** is activated, resulting in a different output on the contacts **4804***a-n*. An example of this two-stage switch **4702** in actual use would be for the generator **904** to have two possible output power levels available, each resulting in a different motion displacement value of the waveguide **1502**. Activation of the first sub-switch **4902** can, for example, initiate the first output power level from the generator **904** and activation of the second sub-switch **4904** could result in a second power level to be output from the generator **904**. An exemplary embodiment of this two stage switch **4702** provides a low-power level for the first displacement and a high-power level for the second displacement. Configuring the sub-switches **4902** and **4904** in a stack, shown in FIG. **49**, advantageously makes it easy and intuitive for an operator to move from the first switch mode, i.e., first power level, to the second switch mode, i.e., second power level, by simply squeezing the plunger **4802** of the button **4702** with increased force.

In one embodiment of the sub-switches **4902** and **4904**, spring force could be utilized, with each spring having a different spring-force rating. When the plunger **4802** is initially depressed, the first spring in the first sub-switch **4902** begins to compress. Because a second spring located in the second sub-switch **4904** is stiffer than the first spring, only the first sub-switch **4902** is caused to change switching states. Once the first sub-switch **4902** is depressed a sufficient distance to change switching states, further (greater) force applied to the plunger **4802** causes the second stiffer spring to depress and the second sub-switch **4904** to change states.

In practice, ultrasonic cutting devices, such as ones employing the present invention, encounter a variety of tissue types and sizes and are used in a variety of surgical procedure types, varying from precise movements that must be tightly controlled to non-delicate cutting material that requires less control. It is therefore advantageous to provide at least two ultrasonic cutting power levels that allow an operator to select between a low-power cutting mode and a higher-power cutting mode. For example, in the low-power cutting mode, i.e., only the first sub-switch **4902** is depressed, the tip of the waveguide **1502** moves at about 0.002 inches of displacement. In the higher-power cutting mode, i.e., both the first and second sub-switches **4902** and **4904** are depressed, the tip of the waveguide **1502** moves at about 0.003 inches of displacement, providing a more robust cutting tool that can move through tissue at a quicker rate or cut though tougher, denser matter quicker than the lower-power setting. For example, cutting through mesentery is generally performed at a more rapid rate at higher power, whereas vessel sealing can be performed at lower power and over a longer period of time.

The present invention, however, is in no way limited to stacked switches and can also include switches that are independent of one another. For instance, the shape of the button **4608** may have a first portion that makes contact with a first low-power switch and a second portion that, upon further movement of the button, makes contact with a second high-power switch. The present invention is to be considered as including any multiple-stage switch that engages different stages by movement of a single button.

In one exemplary embodiment of the present invention, the switch **4702**, **4800** provides a physical resistance analogous to a compound bow. Compound bows, which are well known for shooting arrows at a high rate of speed, have a draw-force curve which rises to a peak force and then lets off to a lower holding force. By recreating this physical affect with the second sub-switch **4904**, the user of the device will find moving into and engaging the first sub-switch **4902** to be rather easy, while moving into the higher-power mode, initiated by depression of the second sub-switch **4904** requiring a higher depression force, to be an occurrence that takes place only by the operator consciously applying an increased force. Once the higher depression force is overcome, however, the force required to maintain the second sub-switch **4904** in the depressed position decreases, allowing the operator to remain in the higher-power mode, i.e., keeping the button depressed, without fatiguing the operator's finger. This compound-bow-type effect can be accomplished in a variety of ways. Examples include an offset cam, overcoming a pin force or other blocking object, software control, dome switches, and many others.

In one exemplary embodiment of the present invention, the switch **4702** produces an audible sound when the switch **4702** moves from the first mode to the second higher-power mode. For example, the audible sound can be emanated from button, itself, or from the buzzer **802**. The sound notifies the operator of entry into the higher-power mode. The notification can advantageously prevent unintended operation of the inventive ultrasonic device.

c. Waveguide Node Bumps

In accordance with an exemplary embodiment of the present invention, as shown in FIG. **57**, at least one bump **5710** is/are provided at a node(s) of the ultrasonic waveguide **1502**. In other words, the bumps **5710** are located at points along the waveguide **1502** where the waveguide **1502** does not exhibit ultrasonic motion at resonant frequency. The bumps **5710** are radially and longitudinally symmetrical and, therefore, the change in diameter of each bump **5710** and its physical waveguide characteristics of decreasing (radially larger) and then increasing (radially smaller) transmitted vibration does not adversely affect the waveguide's ability to resonate at an ultrasonic frequency or to transmit the desired vibration at the distal blade tip. The bumps are discussed in further detail with regards to FIG. **76**.

d. Near-Over-Center Trigger

Referring now to FIGS. **61** to **64**, an exemplary embodiment of a variable-pressure trigger will be shown and described. The components of the variable pressure trigger can be seen in the perspective partial view of the right hand side of the handle assembly **302** illustrated in each of FIGS. **61** to **64**. In this view, several of the internal components are exposed and viewable because much of the shell of the handle assembly **302** is not present. In practice, many of the components shown in FIGS. **61** to **64** are covered by the shell, protected, and not viewable.

Looking first to FIG. **61**, at least a portion of a trigger pivot assembly **6102** is shown. The assembly **6102** includes a first pivoting member **6104** and a second pivoting member **6106**. In the following discussion, a comparison between FIG. **61** and each of FIGS. **62** to **64** will be described that illustrates the interaction between the first pivoting member **6104** and the second pivoting member **6106** as the trigger **4606** is progressively squeezed by an operator.

The first pivoting member **6104** is an elongated structure and has a first end **6112** and a second end **6114**. The first end **6112** of the first pivoting member **6104** is rotationally coupled to a first pivot pin **6116** while the second end **6114** is rotationally coupled to a second pivot pin **6118**. In the perspective view of FIG. **61**, the exemplary embodiment of the first pivoting member **6104** can be seen as including two separate halves, each half coupled to the first pivot pin **6116** and the second pivot pin **6118** and being connected together at a center section. In this embodiment, the center pivot is comprised of a round boss on the trigger that is captured by two links. The two links are hermaphroditic parts and are pressed together so that the boss is constrained by two holes, one on each link. This configuration creates the third pivoting section. There is, however, no requirement that this pivoting member comprise this configuration. The pivoting member can be any structure that couples the two pivot pins **6116** and **6118** and provides the proximally directed force at the first pivot pin **6116** to translate the actuator for the end effector **118**, which end effector **118** will be described in further detail below. As can be seen in FIGS. **61** to **64**, the first pivot pin **6116** rides within a longitudinally extending guide track **6130** shown on the left body half **4603** of the handle assembly **302**, a mirror image of which is similarly present on the opposing right body half **4503**. As the trigger **4606** is depressed, shown in the progression of FIG. **61** to FIG. **62** to FIG. **63** to FIG. **64**, the first pivot pin **6116** translates in the proximal direction a sufficient distance to actuate the end effector **118** from an at-rest position (shown by the first pivot pin position in FIG. **61**) to a fully actuated position (shown by the first pivot pin position in FIG. **64**).

In accordance with the exemplary embodiment shown, the second pivot pin **6118** is coupled to and is part of the trigger **4606**. In particular, the entire second pivoting member **6106**, including the pivot pin **6118**, actually comprises a furthest extent of the trigger **4606**. This furthest extent of the trigger **4606** (the second pivoting member **6106**) is, itself, rotationally coupled to a third (fixed) pivot pin **6110** within the handle assembly **302**. This third pivot pin **6110** defines the axis about which the trigger **4606** rotates with respect to the handle assembly **302**. The third pivot pin **6110** is shared by a sliding rotational-lockout member **6508**, which works in conjunction with a rotational lockout blade. The purpose and details of the rotational lockout blade will be explained in the following section.

Because the position of the third pivot pin **6110** is fixed with respect to the handle assembly **302**, when the trigger **4606** is squeezed by the operator, the first pivot pin **6116** moves away from the third pivot pin **6110**. In addition, as the first pivot pin **6116** is moving away from the third pivot pin **6110**, the second pivot pin **6118** traverses an arc starting at the position shown in FIG. **61**, where the second pivot pin **6118** is well below an imaginary line **6120** connecting the first pivot pin **6116** to the third pivot pin **6110**, to the position shown in FIG. **64**, where the second pivot pin **6118** is much closer to that imaginary line **6120** still connecting the first pivot pin **6116** to the third pivot pin **6110**.

The movement of the trigger **4606** from the position shown in FIG. **61**, through the positions shown in FIGS. **62** through **64** results in a clamping movement of the end effector **118** in a direction towards the waveguide **1502**. In other words, squeezing the trigger **4606** causes the end effector **118** to move from an open position to a closed position (via movement of the outer tube **7302** as described below). Advantageously, interaction between the first pivoting member **6104** and the second pivoting member **6106**, illustrated in a comparison of FIGS. **61** through **64**, provides a trigger motion with varying requisite pressures to maintain trigger depression. This variable pressure linkage (**6110**, **6106**, **6118**, **6104**, **6116**) advantageously reduces fatigue on the operator's hand because, once fully depressed, it requires much less pressure to keep the trigger **4606** in the depressed position as compared to the pressure required to partially depress the trigger **4606** as shown, for example, in FIG. **62**.

More specifically, when an operator first applies pressure to the trigger **4606**, a first force is required to move the second pivot pin **6118** (with reference to the orientation shown in FIG. **61**) upwards. The force required to actuate the end effector **118** is actually longitudinal because the first pivot pin **6116** must move proximally. This force moves the second pivot pin **6118** along an arc that, consequently, moves the first pivot pin **6116** away from the third pivot pin **6110** and defines two force vectors along the pivoting members **6104**, **6106**. The two force vectors, in the position shown in FIG. **61**, are at an angle **6122** of approximately 100° and are indicated with a left-pointing black vector and a right-pointing white vector for clarity.

Turning now to FIG. **62**, it can be seen that the trigger **4606** has been moved from the resting position shown in FIG. **61**. This partial movement occurs when the trigger is squeezed during a typical medical procedure at first tissue contact. As the trigger **4606** is squeezed, i.e., moved toward the handle assembly **302**, the first pivot pin **6116**, the first pivoting member **6104**, the second pivoting member **6106**, and the second pivot pin **6118** all change positions. More specifically, the second pivoting member **6106** rotates about the third pivot pin **6110**, which is fixed in its position. Because the third pivot pin **6110** is fixed, the second pivot pin **6118** begins to swing upward, i.e., toward the imaginary line **6120**. As the second pivot pin **6118** swings upward, a force is applied to the first pivot member **6104**, which translates along the first pivot member **6104** and is applied to the first pivot pin **6116**. In response, the first pivot pin **6116** slides proximally in a direction away from the waveguide assembly **304**. In this first stage of translation, shown in FIG. **62**, the angle of the force vectors **6122** can be seen as having increased from that shown in FIG. **61**.

In FIG. **63**, the trigger **4606** is closed even further. As a result, further movement of the first pivoting member **6104**, the second pivoting member **6106**, the first pivot pin **6116**, and the second pivot pin **6118** occurs. As this movement takes place, the second pivot pin **6118** moves even closer to the imaginary line **6120**, i.e., closer to being collinear with the first **6116** and third **6110** pivot pins. As indicated by the force vectors **6122**, the forces applied to the pivoting member's **6104**, **6106** begin to significantly oppose each other. The exemplary angle between the vectors **6122** is, in this position, approximately 150°.

Finally, in FIG. **64** the trigger **4606** has been squeezed until it makes contact with the battery assembly holding portion of the handle assembly **302**. This is the point of maximum translation of the first pivoting member **6104**, second pivoting member **6106**, and the first pivoting pin **6116**. Here, the force vectors substantially opposite one another, thereby reducing the amount of force felt at the trigger **4606**. That is, as is known in the field of mechanics, maximum force is required when two vector forces are additive, i.e., point in the same direction, and minimum force is required when two vector forces are subtractive, i.e., point in opposite directions. Because, in the orientation shown in FIG. **64**, the vectors become more subtractive than additive, it becomes very easy for the user to keep the trigger **4606** depressed as compared to the position shown in FIG. **61**. The ultimate closed position shown in FIG. **64** is referred to herein as a "near-over-centered" position or as "near over centering." When the trigger **4606** is in the near-over-centered position, the force required to keep the trigger depressed is approximately 45% or less than the force required to initially squeeze the trigger away from the position shown in FIG. **61**.

e. Rotational Lock-Out

The present invention provides yet another inventive feature that prevents rotation of the waveguide assembly **304** whenever ultrasonic motion is applied to the waveguide **1502**. This rotational lockout feature provides enhanced safety by preventing the cutting blade from unintentional rotational movement during a surgical procedure. In addition, prevention of rotation ensures that a solid electrical connection is maintained throughout operation of the device **300**. More specifically, the electrical contacts **5402**, **5404** (e.g., pogo pins) between the generator and the transducer do not have to slide along the transducer's contact rings **5406**, **5408** in order to maintain electrical contact because a fixed electrical connection at one location along the contact rings **5406**, **5408** is maintained during operation by virtue of the rotational lockout. The rotational lockout, according to one exemplary embodiment of the present invention, is accomplished through use of a rotational lockout member **6508** shown in FIGS. **65** and **66**.

Referring first to FIG. **65**, a perspective close-up view of the right hand side of handle assembly **302** is shown with the right-side cover removed. In this view, a rotational lockout member **6508** can be seen positioned adjacent a rotation-prevention wheel **6502** (which is rotationally fixed to the waveguide rotation spindle **3704** and, thereby, to the waveguide assembly **304**). The waveguide assembly **304** is, therefore, able to rotate along its longitudinal axis only if the rotation-prevention wheel **6502** is unencumbered and also able to rotate upon that longitudinal axis.

To prevent revolution of the rotation-prevention wheel **6502**, the rotational lockout member **6508** includes a wheel-engagement blade **6504** that extends therefrom in a direction toward the rotation-prevention wheel **6502**. In the position shown in FIG. **65**, the rotational lockout member **6508** does not interfere with the rotation prevention wheel **6502** because the wheel-engagement blade **6504** is at a distance from the outer circumference thereof. In such an orientation of the blade **6504**, the rotation-prevention wheel **6502**, as well as the waveguide assembly **304**, can freely spin upon the longitudinal axis of the waveguide assembly **304**.

Referring now to FIG. **66**, the rotational lockout member **6508** has been displaced into a rotation blocking position. In this position, the wheel-engagement blade **6504** enters the space between two adjacent castellations **6602** on the outer circumference of the rotation-prevention wheel **6502** and engages the side surfaces of the castellations **6602** if the rotation-prevention wheel **6502** rotates. The rotational lockout member **6508** is fixed in its position within the handle assembly **302** and, because of this connection, the engagement between the wheel-engagement blade **6504** and the rotation-prevention wheel **6502** entirely prevent the rotation-prevention wheel **6502** from rotating about the longitudinal axis of the waveguide assembly **304**. For example, with seventy-two castellations **6602** on the outer circumference, the rotation-prevention wheel **6502** has substantially no rotational play when rotationally locked. FIGS. **67** through **69** show that the wheel-engagement blade **6504** engages the rotation-prevention wheel **6502** only when the button **4608** is depressed, thereby preventing substantially all rotational movement of the waveguide assembly **304** when ultrasonic movement of the waveguide **1502** occurs.

FIG. **67** shows a perspective underside view of the rotational lockout member **6508** within the handle assembly **302**. Once again, the right-hand cover of the handle assembly **302** is removed, thereby exposing several of the internal mechanical components of the handle assembly **302**. These components include the button **4608**, shown here in a transparent view, a U-shaped member **6702** that slidably engages with the rotational lockout member **6508**, and a spring **6704** that biases the U-shaped member **6702** away from a bottom portion of the rotational lockout member **6508**. FIG. **67** shows the rotational lockout member **6508**, the U-shaped member **6702**, and the spring **6704**. In the position shown in FIG. **67**, the spring **6704** is preloaded by pressure that is asserted by the U-shaped member **6702**. The rotational lockout member **6508** is rotationally coupled to and pivots about a pivot pin **6706**, which is fixedly coupled to the handle assembly **302**.

In addition, FIG. **67** shows a torsional spring **6708** that biases the rotational lockout member **6508** away from the castellations **6602** of the rotation-prevention wheel **6502**. The torsional spring **6708** ensures that the natural resting position of the rotational lockout member **6508** is disengaged from the rotation-prevention wheel **6502**. A spring force of the torsional spring **6708** is selected so that it is less than a spring force of the spring **6704**. Therefore, movement of the rotational lockout member **6508** can occur prior to the spring **6704** being fully compressed.

In operation of the rotation prevention system, when the button **4608** is depressed after a short distance, a rear side of the button **4608** physically contacts the U-shaped member **6702** and moves the U-shaped member **6702** as further proximal button movement occurs. In other words, when depressed, the button **4608** imparts a proximal force on the U-shaped member **6702** in a direction against the biasing force of the spring **6704**. This proximal force causes the spring **6704** to compress and allows the U-shaped member **6702** to move in a direction toward the rotational lockout member **6508**. This movement is shown in FIG. **68**, where the U-shaped member **6702** is closer to the rotational lockout member **6508** than the position shown in FIG. **67**. In the view of FIG. **68**, the spring **6704** is no longer visible because the U-shaped member **6702** has moved proximate to the rotational lockout member **6508** to a point that the lockout member **6508** completely obscures the spring **6704** in this view. Such contact without a rigid connection ensures that the lockout mechanism does not impede release of the activation button **4608**, which is critical to safe operation of the device. Additionally, the connection helps to minimize force that the switch will have to release and reduces operator fatigue.

When the button **4608** is further depressed, as shown in FIG. **69**, the rotational lockout member **6508** pivots around the pivot pin **6706** and swings upwardly toward the rotation-prevention wheel **6502**. As this upward swing occurs, the wheel-engagement blade **6504** engages the castellations **6602** of the rotation-prevention wheel **6502**. In other words, the position of the rotational lockout member **6508** shown in FIG. **69** corresponds to the position of the rotational lockout member **6508** shown in FIG. **66**. Similarly, the position of the rotational lockout member **6508** shown in FIG. **67** corresponds to the position of the rotational lockout member **6508** shown in FIG. **65**.

In some circumstances, when the button **4608** is depressed, the wheel-engagement blade **6504** lands on one of the castellations **6602** and does not fall between two of the castellations **6602**. To account for this occurrence, a stroke distance, i.e., the distance the U-shaped member **6702** is able to move towards the rotational lockout member **6508** allows an electrical activation of the device without requiring actual physical movement of the rotational lockout member **6508**. That is, the rotational lockout member **6508** may move slightly, but does not need to fit between two of the castellations **6602** for ultrasonic operation to occur. Of course, rotation is still prevented, as any rotational movement in either direction will cause the rotational lockout member **6508** to move up and into the castellations **6602**.

In a further exemplary embodiment of the present invention, a rotational lockout member **7002**, as shown in FIGS. **70** and **71**, can be provided with one or more blades **7004**, **7006** that engage with an outer surface **7008** of a rotation-prevention wheel **7001**. In this particular embodiment, the rotation-prevention wheel **7001** does not have teeth on its outer circumference, as the embodiment of the rotation-prevention wheel **6502** of FIGS. **65** to **69**. In the embodiment of FIGS. **70** and **71**, the outer surface **7008** of the rotation-prevention wheel **7001** is sufficiently malleable to allow the blades **7004**, **7006** to engage the outer surface **7008**, for example, to actually cut into the outer circumference of the rotation prevention wheel **7001**. However, in certain embodiments, where razor-type blades **7004**, **7006** are utilized, the rotation-prevention wheel **7001** is sufficiently hard to prevent the blades **7004**, **7006** from penetrating more than a predefined depth when an expected amount of force is applied. Furthermore, the lockout member **6508** and U-shaped member **6702** can be, instead, replaced with a single stamped/etched or wireformed lockout member that, within its geometry, replaces at least one of the springs with a flexing feature. FIGS. **105** and **106** show two exemplary embodiments of this alternative configuration.

Once the blades **7004**, **7006** are driven into the outer surface **7008** of the rotation-prevention wheel **7001**, as is shown in FIG. **71**, the rotation-prevention wheel **7001** is rendered unable to rotate about the longitudinal axis of the waveguide assembly **304**. Of course, a single blade or three or more blades can be used to prevent the rotation-prevention wheel **7001** from rotating. By separating and angling the blades **7004** and **7006** from one another, rotation prevention is enhanced in either rotational direction. In other words, when the blades **7004** and **7006** are angled away from one another, rotation of the rotation-prevention wheel **7001**, in either direction, causes one of the blades **7004** or **7006** to dig deeper into the rotation-prevention wheel **7001**. The lockout member **7002** disengages from the rotation-prevention wheel **7001** when pressure is removed from the button, for example, due to a button-return spring. In addition, in this particular embodiment of the rotational-lockout member **7002**, a portion of the rotation-lockout member **7002** may capture the third pivot pin **6110**. Additional ways of preventing the application of energy while rotating are present using electromechanical and electro-optical technologies. Any combination of sensors, such as magnetic position encoders or optical position sensors, could be used to stop application of energy to the waveguide **1502** if rotation is detected or can be used as a trigger to engage a mechanical lockout such as a solenoid or knife switch. These mechanical measures can also be used without the sensors and can lockout rotation during any energy application. Optical encoders could be placed within the generator housing and directed outward through windows to watch for motion of the transducer housing. Magnetic encoders can be completely buried within the enclosures to further reduce leak path risk.

XIII. TAG—Mechanical

Referring to FIG. **50**, the reusable TAG assembly **303** is shown separate from the handle assembly **302**. The inventive TAG assembly **303** includes a transducer horn **5002** with an ultrasonic waveguide couple **5004** that is configured to attach a waveguide securely thereto and, upon activation of the transducer horn **5002**, to excite the attached waveguide, i.e., impart ultrasonic waves along the length of the waveguide.

In this exemplary embodiment, the waveguide couple **5004** is female and includes interior threads, which are used to secure the TAG assembly **303** to the waveguide **1502** (see, e.g., FIG. **45**) by screwing an end of the waveguide **1502** onto the threads of the waveguide couple **5004** with a predefined amount of torque. The torque should be sufficient so that a mechanical connection created by the torque is not broken during normal operation of the device. At the same time, the torque applied to couple the threads should not exceed a force that will cause the threads to become stripped or otherwise damaged. During initial coupling of the transducer **902** and waveguide **1502**, all that is needed is that one of the transducer **902** and waveguide **1502** remains relatively stationary with respect to the other. The waveguide rotation spindle **3704** is rotationally fixedly coupled to the transducer **902**, which, together, are rotationally freely connected to the body **5005** of the TAG assembly **303**. As such, the waveguide rotation spindle **3704** and the transducer **902** are both able to freely rotate with respect to the body **5005**. To make the waveguide-transducer connection, therefore, the waveguide **1502** can be held stationary as the waveguide rotation spindle **3704** is rotated to couple the interior threads of the transducer horn **5002** with the corresponding male threads at the proximal end of the waveguide **1502**. Preferably, the waveguide **1502** is coupled, i.e., screwed onto the threads of the waveguide couple **5004** to a point where the mechanical connection is sufficient to transfer the mechanical ultrasonic movement from the TAG assembly **303** to the waveguide **1502**.

In one exemplary embodiment of the present invention, a torque wrench **8800** (see FIG. **88**) couples to the waveguide rotation spindle **3704** and allows the user to rotate the spindle **3704** to a predetermined amount of torque. Once the rotational coupling pressure between the waveguide couple **5004** and the waveguide **1502** exceeds a predetermined amount of torque, the outer portion of the torque wrench **8810** slips about an inner portion **8820** and, thereby, the spindle **3704**, and no further rotation of the spindle **3704** takes place. Through use of the inventive torque wrench **8800**, an operator is able to apply precisely the proper amount of tension to the junction between the TAG assembly **303** in the waveguide **1502** and is also prevented from damaging the threads on either the waveguide couple **5004** or on the waveguide **1502**.

This exemplary embodiment of the torque wrench also clips onto the spindle **3704** to prevent any possibility of the wrench slipping off of the TAG assembly **303** without outside force acting upon it. More specifically with regard to FIG. **50**, the spindle **3704** is provided with wrench-gripping surfaces **5014** disposed circumferentially about the proximal end of the spindle **3704**. In this exemplary embodiment, the wrench-gripping surfaces **5014** are indentations. The inner portion **8820** of the torque wrench **8800** is, conversely, provided with flexible tines **8822**, each having an inner distal surface defining a spindle-gripping surface **8824**. In this exemplary embodiment, the spindle-gripping surfaces **8824** have somewhat convexly hemispherical-shaped protrusions that have a corresponding shape to concavely hemispherical-shaped indentations of the wrench-gripping surfaces **5014**. In this way, as the inner portion **8820** is coupled to the proximal end of the spindle **3704**, each tine **8822** of the inner portion **8820** flexes outwardly and, then, snap back to place the corresponding protrusions **8824** of the tines **8822** within the respective indentations **5014**. The user can, then, release the outer portion **8820** completely and the wrench **8800** remains on the spindle **3704** for as long as needed until removal is desired.

To enable coupling of the inner and outer portions **8810**, **8820** of the torque wrench **8800** to remain rotationally coupled to one another until a predetermined amount of torque exists, the outer portion **8810** is provided with a ratchet gear **8812** and the inner portion **8820** is provided with a ratchet **8826**. The slope and inward-extent of the gear **8812** and the outer circumference and tooth size of the ratchet **8826** are selected to slip at a predetermined amount of torque. With use of sufficiently resilient materials, the torque value at which the two portions **8810**, **8820** slip with respect to one another, can be set with great accuracy. Through use of the inventive torque wrench **8800**, an operator is able to apply precisely the proper amount of tension to the junction between the TAG assembly **303** in the waveguide **1502** and is also prevented from damaging the threads on either the waveguide couple **5004** or on the waveguide **1502**. To counter the torque of the torque wrench the operator must hold the rotation wheel while rotating the torque wrench. For this operation, in an exemplary embodiment, a lockout button can be integrated into the handle halves. This lockout button is depressed by the operator and, when depressed, engages the rotation prevention wheel, stopping the free rotation of the shaft assembly with minimal applied force.

The TAG assembly **303** also has a housing comprised of an upper housing portion **5020** and a lower housing portion **5030** that protects and seals the internal working components from the environment. See FIGS. **50** and **53**. Because the TAG assembly **303** will be in the sterile field of the operating environment, it is sterilizable, advantageously, by vapor phase hydrogen peroxide, for example. As such, the seal between the upper housing portion **5020** and the lower housing portion **5030** is aseptic and/or hermetic.

According to one exemplary, non-illustrated embodiment of the present invention, the transducer **902** is located entirely inside the housing **5005**—where it cannot be readily secured by the operator, for example, by holding it steady by hand when the waveguide assembly **304** is being secured. In such an embodiment, the TAG assembly **303** is provided with a transducer rotation lock. For example, the transducer rotation lock can be a button that slides into a recess in the housing **5005** or, alternatively, by fixing the rotation of the transducer **902** at a maximum rotational angle so that, once the maximum rotation is reached, for example, 360 degrees of rotation, no additional rotation is possible and the waveguide assembly **304** can be screwed thereon. Of course, a maximum rotation in the opposite direction will allow the waveguide assembly **304** to be removed as well. In another exemplary embodiment, the torque wrench is incorporated into the handle itself. This exemplary embodiment is not illustrated but can be understood from looking at FIGS. **87** and **88**. As can be seen in FIG. **88**, one possible torque-limiting device is configured with an inner ratchet portion **8826** and a ratchet gear **8812**. This ratcheting assembly can be built into the rotation prevention wheel **6502**, a portion of which is shown in FIG. **87**. If this rotation prevention wheel **6502** is made of an inner radial part and an outer radial part, the two parts being able to rotate with respect to one another, then either can be formed with one of the inner ratchet portion **8826** with the other one being formed with the ratchet gear **8812**. In this way, a user could hold the proximal knob of the transducer still and use rotation of the spindle **3704** to connect the waveguide and the transducer together. When the desired torque is reached, the inner ratchet portion **8826** and the ratchet gear **8812** would slip to prevent over torque. After the waveguide is connected to the transducer with the correct amount of torque, use of spindle rotation during a procedure will not be affected as the number of pounds needed to rotate the spindle **3704** is far less than the number of pounds that is required to overcome torque ratcheting feature.

The housing **5005** has a securing connection **5012** shaped to selectively removably secure to a corresponding connector part of the handle assembly **302**. See, e.g., FIG. **56**. The connection **5012** can be any coupling connection that allows the TAG assembly **303** to be removably attached and secured to the handle assembly **302**, such as the exemplary "dove-tail" design shown in FIGS. **50** to **53** and **56**. In FIG. **56**, a TAG-retention device **5604** is provided. The TAG-retention device **5604** is a mechanical feature that stops the TAG assembly **303** from sliding off of the handle assembly **302** under its own weight. The retention device **5604** imparts friction to the securing connection **5012** that makes it hard to pull the TAG assembly away from the disposable without overcoming at least a force greater than the weight of the TAG assembly **303**. The TAG-retention device **5604** can be in the form of a finger, as shown in FIGS. **61** to **64** and **86**, or one or more bumps that interfere with the slide rail. The force that is required to separate the two parts prevents accidental dropping of the TAG assembly **303** during exchange or removal. The area of contact between the handle assembly **302** and the TAG assembly **303** can be sealed so that, in the event of surgical fluids contacting the TAG assembly **303**, they will not introduce themselves into the interior of the TAG attachment dock **4502**.

It is advantageous for the TAG assembly **303** to be selectively removable from the handle assembly **302**. As a separate component, the TAG assembly **303** can be medically disinfected or sterilized (e.g., STERRAD®, V-PRO®, autoclave) and reused for multiple surgeries, while the less-expensive handle assembly **302** itself may be disposable. In addition, the TAG assembly **303** can be used in multiple handles or in the same handle up to a desired maximum number of times before it is required to be disposed. In a further embodiment, the transducer **902** of the TAG assembly **303** can be selectively removable from the generator **904** allowing for better access for cleaning. In such an embodiment, the benefits provided by the invention to matching a transducer to a generator can be maintained by configuring the transducer with a communication system that sends to the generator the transducer's calibration coefficients.

FIGS. **51** and **52** provide two additional perspective views of the TAG assembly **303**. FIG. **52** depicts an exemplary display window for a user display system (for example, RGB LED(s) **906**) on the external surface of the housing **5005** of the TAG assembly **303**. As explained above, the RGB LED **906** provides various signaling to the user indicating conditions and modes of the surgical assembly **300**. Various conditions and modes displayed to the user can also include an indication that the battery level on installation is inadequate—it does not have enough energy to perform the start-up check and initiate software—or that the battery itself is bad. Positive displays can include proper start-up—that, upon connection of the battery to the TAG, there is proper power, verified by battery/TAG communications and, possibly, the amount of available TAG life—or that the system is ready and idling for use. Activation of both the low and high modes can be displayed. With regard to the TAG, expiration of life or other TAG-related faults can be displayed. With regard to the battery, a low condition can be indicated after the battery is connected or during its use. The display can indicate, for example, if the battery only has approximately 20% of charge remaining when first attached. An end of battery charge or other battery faults can be indicated. Finally, various system faults including general faults, battery or TAG software being non-functional, can be displayed.

FIG. **53** provides a top view of the TAG assembly **303** with the upper housing portion **5020** removed, thereby exposing the generator circuitry of the TAG assembly **303**, see, e.g., FIG. **9**. In a further exemplary embodiment, the generator circuitry includes a memory electrically connected at least to the processor of the TAG assembly **303** or to the processor in the battery assembly **301** (or integrated in any circuit thereof). The memory can be used, for instance, to store a record of each time the TAG assembly **303** is used. Other data relevant to the TAG assembly **303** and/or the waveguide assembly **304** and/or the housing assembly **302** and/or the battery assembly **301** can be stored as well for later access and analysis. This record can be useful for assessing the end of any part of the device's useful or permitted life, in particular, the TAG assembly **303** itself. For instance, once the TAG assembly is used twenty (20) times, the TAG assembly **303** or the battery assembly **301** can be programmed to not allow a particular handle or battery to function with that "old" TAG assembly (e.g., because the TAG assembly **303** is, then, a "no longer reliable" surgical instrument). The memory can also store a number of uses any of the device's peripherals. For an illustrative example only, after a certain number of uses, it is possible that one of the parts of the device can be considered worn, as tolerances between parts could be considered as exceeded. This wear could lead to an unacceptable failure during a procedure. In some exemplary embodiments, the memory stores a record of the parts that have been combined with the device and how many uses each part has experienced.

At times, it may be desirable to provide feedback to the user even when the TAG assembly **303** is disconnected from the battery assembly **301**, such as the "end of life" or "no longer reliable" indications of the TAG assembly **303**, which indications require that the TAG assembly **303** be taken out of circulation because it has exceeded its useful life and can no longer be used. As is often the case, the physician may not be the same person who is responsible for the proper assembly of the device or for removing the TAG assembly **303** from the device. Accordingly, the TAG assembly **303** can be beneficially configured to have a persistent indicator having its own power source separate from the battery assembly **301**. This indicator provides an "end of life" termination warning following the most recent (or last) mating between the TAG assembly **303** and a battery assembly **301** to prompt an immediate disposal of the TAG assembly **303** before any wasteful energy is used in subsequently mating the spent TAG assembly **303** to the same or a different battery assembly **301** for use. Or, alternatively, the indicator could provide the warning immediately upon being subsequently mated to another battery assembly **301** so that it may be disposed of before starting up the device. In either implementation, the warning will be preserved for the party responsible for assembling the device. Multiple schemes can be devised to provide the end-of-life indication to the user, such as primary cells, super capacitors or displays that do not require or draw power. For example, a super capacitor and an ultra-low-power LED drive can be used to provide a strobing indicator. These circuits consume current in the micro-amp range and, therefore, can provide a reliable indication for a number of hours or even days.

In some exemplary embodiments, a memory exists at the battery assembly **301**, and the handle assembly **302** is provided with a device identifier that is communicatively coupled at least to the battery assembly **301** and is operable to communicate to the smart battery **301** at least one piece of information about the ultrasonic surgical assembly **300**, such as the use history discussed in the preceding paragraph, a surgical handle identifier, a history of previous use, and/or a waveguide identifier. In this way, a single smart battery assembly **301** can record use information on a number of different handle and TAG assemblies **302**, **303**. When the battery assembly **301** is placed into a charging unit, such a memory can be accessed and the data about each part of the system **301**, **302**/**304**, **303** can be downloaded into the charger and, if desired, transmitted to a central facility that is communicatively coupled (e.g., through the Web) to the charging station.

FIG. **54** shows one example of how the generator **904** and the transducer **902** are electrically and physically coupled so that a physical rotation of the transducer **902** with respect to the generator **904** is possible. In this example, the generator **904** has a pair of contacts **5402**, **5404** protruding from its underside, adjacent the transducer **902**. The contacts **5402**, **5404** can be connected to the TAG housing in any way. The illustrated exemplary embodiment captures the contacts **5402**, **5404** in place between the generator board and a portion of the TAG housing. As can be seen, the TAG housing is defined by an upper generator housing **5410** and a lower transducer housing **5430**. The generator housing has an upper housing portion **5020** and a lower housing portion **5030**. To install the contacts **5402**, **5404**, therefore, the contacts **5402**, **5404** are placed into the lower housing portion **5030** and are sealed in place by o-rings (shown) or adhesive. The generator board **5460** is then set on top of the contacts **5402**, **5404** and mated for electrical contact. As the upper housing portion

5020 placed on the TAG assembly, it has features that hold the generator board 5460 in place, thereby trapping the contacts 5402, 5404 from moving. These features on the upper housing portion 5020 can be, for example, fingers that push against the board 5460 itself or push on larger components on the generator board 5460. Additionally compressive materials can be used to take up tolerances therebetween and reduce the ability of the board to move around and potentially cause intermittent contact with the connections.

Proximity of the transducer 902 to the generator 904 places one of the pair of contacts 5402, 5404 in physical communication with a corresponding pair of contact rings 5406, 5408 on the body of the transducer 902 so that a driving signal can be steadily and reliably applied to the transducer 902 when needed. Advantageously, the pair of contacts 5402, 5404 maintains electrical contact regardless of the angle of rotation of the transducer 902. Therefore, in this exemplary embodiment, the transducer 902 can rotate without any limitation as to the maximum angle or number of rotations. Additionally, the rings 5406, 5408 and contacts 5402, 5404 ensure that the transducer 902 remains in electrical contact with the generator circuitry regardless of the point of rotation at which the torque wrench stops the tightening the transducer 902 to the waveguide 1502. In an exemplary embodiment that helps alleviate wear between the contact rings and the contacts, the rings are provided with a highly polished surface finish. Also since the contacts are spring-loaded, the contacting spring force is minimized to reduce contact forces and, ultimately, friction. With a smooth surface and a low pin-pushing force, the friction is kept to a minimum, thereby minimizing wear between the two rotating parts. This, along with the plating process, ensures that electrical connection between the mating parts is not interrupted.

The transducer housing 5430 is also made of two parts, a proximal housing portion 5432 and a distal housing portion 5434. As can be seen well in FIG. 50, the lower housing portion 5030 has two housing rings 5416, 5418 that rotatably secure the transducer housing 5430 to the generator housing 5410. The proximal housing ring 5418 merely radially captures the circular outer-diameter proximal transducer portion 5432. It is the distal housing ring 5416 that both radially and longitudinally captures the transducer 902. More specifically, a proximal o-ring 5440 on the proximal side of the distal housing ring 5416 provides one part of the longitudinal capture and a fastener 5442 on the distal side of the distal housing ring 5416 provides the other part of the longitudinal capture. The fastener 5442 can be, for example, one or more snap rings. With this secure longitudinal capture, the two transducer contact rings 5406, 5408 become longitudinally aligned with the two contacts 5402, 5404 for a secure electrical connection between the generator 904 and the transducer 902.

As shown in FIG. 37, the surgical handle assembly 302 has a spindle 3704 attached to the waveguide assembly 304. The spindle 3704 has indentions that allow a surgeon to easily rotate the spindle 3704 with one or more fingers and, therefore, to correspondingly rotate the attached waveguide assembly 304 and the transducer 902 connected to the waveguide 1502. Such a configuration is useful for obtaining a desired cutting-blade angle during surgery.

FIG. 55 shows one exemplary embodiment of the TAG assembly 303 where the body 5005 and the transducer's shell have been removed. When a voltage is applied to the piezoelectric crystal stack 1504, the horn 5002 moves longitudinally within and relative to the housing 5020, 5030. In this embodiment, the waveguide coupler 5004 is female and includes internal threads (not visible in this view), which are used to secure the TAG assembly 303 to the waveguide 1502 (not illustrated here) by screwing the waveguide 1502 into the threads with an appropriate amount of torque.

A novel feature of the TAG assembly 303 is its ability to mechanically and electrically connect at the same time. FIG. 56 shows an exemplary embodiment of the TAG assembly 303 in the process of docking with the handle assembly 302. At the same time the transducer 902 is being coupled to a waveguide 1502 (attached to the handle assembly 302), the TAG assembly's electrical connector 5010 is brought into contact with the handle assembly's electrical connector 5602. The coupling of the TAG's electrical connector 5010 with the handle's electrical connector 5602 places the piezoelectric crystal stack 1504 in electrical communication (direct or indirect) with the battery assembly 301 docked with the handle assembly 302, as shown in FIG. 37 for example. This substantially simultaneous coupling can be configured to occur in all embodiments of the present invention. The pins of this connection are unique and are shown well in the left side of FIG. 54. Here, a single right angle pin is overmolded into the plastic generator housing 5030 to thereby create pins for the connector 5010. Likewise, these pins each extend upwards into the interior of the generator enclosure to make connection to the generator circuit board 5460. The circuit board connection can be accomplished with solder or, in a simpler form, through sockets mounted to the generator board 5460. In this way, the assembly process is simplified when combined with the sockets that make the connection to the electrodes (pogo pins) 5402, 5404 of the transducer 902. The assembly of the generator housing 5410, therefore, becomes a matter of merely placing the generator board 5460 over the arrays of vertical pins and sealing the housing 5410. Protrusions extending upward from the lower housing portion 5030 support the circuit board 5460 laterally and providing the upper housing portion 5020 with similar protrusions completely trap the generator board 5460 therebetween. Visual outputs from the generator 904 are made through translucent windows 5410 in the upper housing portion 5410. LEDs are strategically placed on the generator 904 to allow illumination of the windows. The space between the LEDs and the windows allows for the light to spread over a larger area and addition of diffusing materials at the windows makes the illumination even. In an exemplary embodiment, the windows wrap around the upper curved surface of the upper housing portion 5020 to be visible over a wide range of viewing and operating angles.

In accordance with further exemplary embodiments of the present invention, the TAG assembly 303 provides a mechanical connection prior to establishing an electrical connection. That is, when attaching the TAG assembly 303 to the handle 302, a mechanical connection is established between the waveguide 1502 and the ultrasonic waveguide couple 5004 prior to an electrical connection being made between the TAG assembly's electrical connector 5010 and the handle assembly's TAG electrical connector 5602. Advantageously, because an electrical connection is not made until after the mechanical connection is established, electrical “bouncing” is avoided in this embodiment. More specifically, as the threads 8604 of the waveguide 1502 couple to the ultrasonic waveguide couple 5004, the electrical connection being made after a solid mechanical connection insures that the TAG assembly's electrical connector 5010 and the handle assembly's electrical connector 5602 to the TAG are in a fixed positional relationship, at least momentarily, and instantaneous removal and reestablishment of the electrical connection will not take place. Similarly, when the assembly 300 is being disassembled, the electrical connection is broken prior to a full separation of the mechanical connection.

The electrical connector **5602** of the handle **302** is best shown in FIGS. **86** and **108**. The electrical connection occurs as the TAG assembly **303** is being mechanically joined to the handle **302**. The electrical connector **5010** of the TAG assembly **303** can be seen in FIGS. **50** and **54** and includes a chamfered rectangular blind hole having conductive pins **5470** extend out from the bottom of the hole centered along the longitudinal extent of the hole. The electrical connector **5602** of the handle **302** can be seen in FIGS. **86** and **108** as including a conductor rail **8630**, a soft gasket **8632**, and a stiff backing **8634**, which also is a stiffening part of the flex circuit harness **3516** electrically connecting the electrical connector **5602** of the handle **302** to the flex circuit board **3514** at the multi-lead handle terminal assembly **3502**.

Contact occurs first between the electrical connector **5010** of the TAG assembly **303** and a soft gasket **8632**. Further coupling compresses the gasket **8632**, which compression against the stiffer portion **8634** of the flex harness **3516** creates a fluid-tight seal between the connector **5010** and the flex harness **3516**. This connection fully surrounds the connector rail **8630** and prevents fluid from being able to enter any gap between the connector **5010** and the stiffener **8634**. The pins **5470** of the connector **5010** that insert into the conductor rail **8630** are, themselves, potted to prevent fluid contact with the interior of the generator **904**. This same configuration is used to create the seal between the handle **302** and the housing of the battery **301**.

In accordance with other exemplary embodiments of the present invention, the ultrasonic surgical device **300** is able to accept and drive a plurality of waveguide types, e.g., having varying dimensions. Where the handheld ultrasonic surgical cautery assembly **300** is able to accept and drive waveguides **1502** of varying types/dimensions, the handheld ultrasonic surgical cautery assembly **300** is provided with a waveguide detector coupled to the generator **904** and operable to detect the type (i.e., the dimensions or characteristics) of the waveguide **1502** attached to the transducer **902** and to cause the generator **904** to vary the driving-wave frequency and/or the driving-wave power based upon the detected waveguide type. The waveguide detector can be any device, set of components, software, electrical connections, or other that is/are able to identify at least one property of a waveguide **1502** connected to the handheld ultrasonic surgical cautery assembly **300**.

XIV. Waveguide Assembly

FIGS. **73** to **87** provide detailed illustrations of exemplary embodiments of the waveguide assembly **304**. The waveguide assembly **304** receives ultrasonic movement directly from the transducer **902** when the waveguide **1502** is physically coupled to the TAG assembly **303**. The blade portion **7304** of the waveguide **1502** transfers this ultrasonic energy to tissue being treated. The ultrasonically-moving blade portion **7304** facilitates efficient cutting of organic tissue and accelerates blood vessel clotting in the area of the cut, i.e., accelerated coagulation through cauterization.

Referring to FIG. **73**, a perspective partial view of the distal end **7306** of the waveguide assembly **304** is shown. The waveguide assembly **304** includes an outer tube **7302** surrounding a portion of the waveguide **1502**. A blade portion **7304** of the waveguide **1502** protrudes from the distal end **7306** of the outer tube **7302**. It is this blade portion **7304** that contacts the tissue during a medical procedure and transfers its ultrasonic energy to the tissue. The waveguide assembly **304** also includes a jaw member **7308** that is coupled to both the outer tube **7302** and an inner tube (not visible in this view). The jaw member **7308**, together with the inner and outer tubes **7302**, **7402** and the blade portion **7304** of the waveguide **1052**, can be referred to as an end effector. As will be explained below, the outer tube **7302** and the non-illustrated inner tube slide longitudinally with respect to each other. As the relative movement between the outer tube **7302** and the non-illustrated inner tube occurs, the jaw **7308** pivots upon a pivot point **7310**, thereby causing the jaw **7308** to open and close. When closed, the jaw **7308** imparts a pinching force on tissue located between the jaw **7308** and the blade portion **7304**, insuring positive and efficient blade-to-tissue contact.

FIG. **74** provides a perspective underside view of the distal end **7306** of the waveguide assembly **304** shown in FIG. **73** with the outer tube **7302** removed. In this view, a distal end **7306** of the inner tube **7402** can be seen coupled to the jaw **7308**. This coupling is provided by, in the exemplary embodiment illustrated in FIG. **74**, a union of a pair of bosses **7408** on the jaw **7308** with boss-engaging openings **7414** in each of a pair of clevis arms **7418**, **7420** that capture the bosses **7408** when the jaw **7308** is inserted therebetween. This relationship is better shown in the cross-sectional perspective underside view of FIG. **75**. From this view, it can be seen that the boss-engaging openings **7414** of the clevis arms **7418**, **7420** of the inner tube **7402** are coined **7502**. The coined clevis arms **7418**, **7420** provide a solid connection between the inner tube **7402** and the jaw **7308**. By coining the openings **7414**, the inner tube **7402** is able to engage the bosses **7408** on the jaw **7308** without having to rely on the outer tube **7302** for structural pressure/support.

FIG. **75** also shows that the waveguide **1502** is separate from, i.e., not attached to, the jaw **7308** or inner tube **7402**. In other words, the waveguide **1502**, when energized with ultrasonic energy, will move relative to the inner tube **7402** and jaw **7308** but will not contact the inner tube **7402** and will only contact the jaw **7308** if the latter is pivoted against the blade portion **7304** without the presence of tissue therebetween. Features of the present invention that facilitate this independent movement of the waveguide **1502** will be described below.

Returning to FIG. **74**, the jaw **7308** is provided with a pair of flanges **7422**, **7424** at a proximal end **7426** thereof. The flanges **7422**, **7424** extend and surround the waveguide **1502** on opposing sides thereof. Each one of the flanges **7422**, **7424** has, at its end, a pivot control tab **7411**, **7412**, respectively, extending below the waveguide **1502** when the bosses **7408** of the jaw **7308** are secured within the boss-engaging openings **7414** in the clevis arms **7418**, **7420**. It is not a requirement for the pivot control tabs **7411**, **7412** to extend below the waveguide **1502** as shown in FIG. **74**; this configuration exists in the exemplary embodiment shown.

The jaw **7308** may be lubricated to reduce friction between the pivot control tabs **7411**, **7412** and the outer tube **7302**, as well as the bosses **7408** and the inner tube **7402**. Such lubrication permits smoother actuation and reduces wear between the mating faces. Lubrication also allows the proximal side of the pivot control tabs **7411**, **7412** to have a tighter fit and a more precise profiling with the outer tube **7302**, which reduces backlash on the jaw **7308**. To avoid rapid displacing of topically applied lubricants, one exemplary embodiment of the lubricant is a baked-on PTFE lubricant. This exposed lubricant on the top surface of the jaw further aids in the insertion of the device through a trocar. In the exemplary embodiment depicted, the pivot control tabs **7411**, **7412** are shown as two arms that straddle the waveguide **1502**. However, the same function can be achieved with a single arm that wraps around the waveguide **1502** and interacts with the outer tube **7302** on a bottom centerline. In both cases, the bottom of the control tab(s) **7411**, (**7412**) are rounded to match a maximum shaft diameter and allow for insertion into trocar, as well as reducing the presence of sharp edges.

Returning briefly back to FIG. **73**, the elevational end view of the waveguide assembly **304** shows that the pivot control tabs **7411**, **7412** of the flanges **7422**, **7424** of the jaw **7308** engage a pair of openings **7311**, **7312** in a distal portion **7306** of the outer tube **7302**. These features are better illustrated in the fragmentary, cross-sectional side view of FIG. **77**.

Because the view of FIG. **77** is a cross-sectional view, only one **7424** of the two flanges **7422**, **7424** is shown and the surface shown is an inside surface of the flange **7424**. Correspondingly, only one of the pivot control tabs **7412** is shown, as well as a single one of the pair of openings **7312** in the distal portion **7306** of the outer tube **7302**. This view makes clear that the opening **7312** surrounds and captures the pivot control tab **7412**. Therefore, if the outer tube **7302** is moved toward the jaw **7308**, the opening **7312** will also move relative to the jaw **7308**. Conversely, if the outer tube **7302** is moved away from the jaw **7308**, the opening **7312** will also move relative to the jaw **7308** in the opposite direction. The captured pivot control tab **7412** nested within the opening **7312** causes a corresponding rotational movement of the jaw **7308** around the pivot point **7310**.

FIG. **78** provides an elevational partial side view of the end effector of the waveguide assembly **304**. This view shows the outer tube **7302** substantially covering the flange **7422** of the jaw **7308**, leaving only the pivot control tab **7411** extending from the opening **7311**. It should now be apparent that, when the outer tube **7302** is slid in a proximal direction **7702**, i.e., in a direction away from the jaw **7308**, the outer tube **7302** will pull the pivot control tabs **7411**, **7412** in the proximal direction **7702**. This action causes the jaw **7308** to pivot around the pivot point **7310** clockwise in FIG. **78** to close, i.e., clamp, toward the blade portion **7304** of the waveguide **1502**. This closed position of the jaw **7308** is shown in FIG. **79**. The configuration of the exemplary embodiment of the waveguide assembly **304** is advantageous because assembly can occur without riveting or welding; the parts are all mechanically captured—e.g., the pivot control tab **7411**, **7412** falls into the opening **7311** to allow the waveguide to be locked in mechanically without riveting or welding. This assembly procedure is discussed in further detail below.

FIG. **80** provides another view of the distal end of the jaw **7308** in a slightly closed position where the jaw **7308** is about to be placed in contact with the blade portion **7304** of the waveguide **1502**. The end effector traps tissue between an interior of the jaw member **7308** and an opposing surface of the blade portion **7304**. Trapping tissue in this way advantageously places the tissue in solid physical contact with the waveguide **1502**. Accordingly, when the waveguide **1502** moves ultrasonically, the movement of the waveguide is directly transferred to the tissue, causing a cut, a cauterization, or both. It has been discovered to be beneficial to create an interference that will account for a deflection of the blade portion **7304** of the waveguide **1502** under the clamping forces imparted at the end effector. Deflection of the waveguide **1502** is a combination of bending and compression of a distal seal (i.e., a coupling spool **8104**). Even though the configuration of the distal seal of the invention minimizes a thickness of elastomeric support, deflection of the waveguide **1502** can be substantial. If the initial contact between the blade portion **7304** and a liner **7314** of the end effector jaw **7308** was parallel, a gap would open at the root of the jaw **7308** as the waveguide **1502** deflected. Therefore, the invention configures initial contact to apply force at the root of the jaw **7308** and come into parallel with the blade portion **7304** when the full clamping force is applied. FIG. **80** shows an exemplary embodiment of the cutting profile of the cutting blade **7304**. To achieve desired tissue or vessel cutting and cauterizing/sealing (excluding clamp force, displacement, and frequency), the cutting blade **7304** contains a composite of high and low stress concentrations between the profile of the blade portion **7304** and the liner **7314** of the jaw **7308**. For desired vessel sealing, the vessel needs to have a seam where the top and the bottom of the vessel are bonded to each other. The seam needs to be centrally cut and a relief volume is desired to allow tissue to flow when sealing and to not char or burn. The profile shown in FIG. **80** provides both desirable characteristics. First, the blade profile features a narrow, relatively flat spine section **8002** that concentrates pressure from the clamping force to a localized seam at a level that allows tissue to momentarily dwell to allow coagulation and eventual cutting. During this dwell time (i.e., the sealing process) adjacent tissue is displaced by providing a curved side profile **8004** away from the cut. The high stress seam on the top and bottom of the blade portion **7304** is used to aid dissection (i.e., back scoring). During the cutting/sealing of tissue or a vessel, it can be beneficial to track tissue/vessel integrity. The invention utilizes the metallic waveguide **1502** as one pole of a two-pole electrical circuit to measure properties such as impedance and/or capacitance of the tissue at the blade portion **7304** of the waveguide **1502**. The electrically conductive material of the waveguide **1502** is already electrically connected to the TAG. This connection forms the first of the two-pole measurement circuit. The opposing pole is part of the liner **7314** in the jaw **7308**. In an exemplary embodiment, a separate electrically conductive lead or other electrically conductive components in the handle **302** can connect the liner **7314** to the TAG.

To facilitate outer tube **7302** translation, and with reference back to FIG. **74**, one or more corsets **7404** are provided on the inner tube **7402**. The corset **7404** is an area of the inner tube **7402** having a smaller diameter D' than the average outer diameter D of the inner tube **7402**. See FIG. **74**. In accordance with an exemplary embodiment of the present invention, the corset **7404** is/are provided at a node(s) of the ultrasonic waveguide **1502**. In other words, the corsets **7404** are located at points along the waveguide **1502** where the waveguide **1502** does not exhibit ultrasonic motion at resonant frequency. Therefore, the decreased diameter of the inner tube **7402** and its physical coupling to an interior surface of the outer tube **7302** does not adversely affect the waveguide's ability to resonate at an ultrasonic frequency. As also illustrated in FIGS. **74** and **75**, for example, a seal **7406** resides within the corset **7404**. The seal **7406**, according to one exemplary embodiment, is an elastomeric O-ring type seal. Of course, many other materials may be selected as well. The seal **7406** has an outer diameter sufficiently larger than the outer diameter D of the **7402** so that the sealing effect is maintained but not too much to prevent the outer tube **7302** and the inner tube **7402** from translating with respect to one another without substantial friction when the jaw **7308** is actuated.

As is also shown in FIGS. **74** and **75**, a thickness of the seal **7406** is smaller than a longitudinal length of the corset **7404** in which the seal **7406** resides. This difference in dimension allows the seal **7406** to travel along the longitudinal extent of saddle **7426** when shaped, as shown, as an annulus having a substantially circular cross-section. In particular, this traveling feature of the seal **7406** takes place when the outer tube **7302** is translated with respect to the inner tube **7402**. Even more specifically, the seal **7406** is dimensioned, i.e., has an annular height, to bridge a gap between an inner surface of the outer tube **7302** and the saddle **7426** of the inner tube **7402** as shown in FIGS. **75** and **77**. By filling this gap completely, the seal **7406** at the distal end **7306** of the waveguide assembly **304** prevents intrusion of moisture or other contaminants within the region between the outer tube **7302** and the inner tube **7402**. Nonetheless, as the outer tube **7302** is translated, the tight fit between the outer tube **7302**, the inner tube **7402**, and the seal **7406** causes the seal **7406** to translate (e.g., roll or slide) within the saddle **7426** while, at all times maintaining a water-tight seal between the outer tube **7302** and the inner tube **7402**. This translation T is illustrated, for example, with the thick arrows in FIG. **77**.

Referring now to FIG. **81**, the distal end of the waveguide assembly **304** at the saddle **7426** is shown in cross-section. This view shows the outer tube **7302** surrounding the inner tube **7402** and the seal **7406** disposed therebetween in the saddle **7426** of the corset **7404**. As explained, the deformable seal **7406** is a water-tight connection between the inner wall **8102** of the outer tube **7302** and the outer surface of the saddle **7426** to prevent moisture or other contaminants from passing from a distal side **8108** of the seal **7406** to a proximal side **8110** of the seal **7406**. FIG. **81** also shows a cross-section a coupling or sealing spool **8104**. The coupling spool **8104** encircles a distal portion of the waveguide **1502** and is disposed at substantially the same longitudinal location as the corset **7404**. As stated above, the corset **7404** is located at or substantially near an ultrasonic-movement node of the waveguide **1502**. Therefore, the coupling spool **8104** is also located at or substantially near that node of the waveguide **1502** and, likewise, does not couple with the waveguide **1502** to receive ultrasonic movement. The coupling spool **8104** provides a support structure that physically links the waveguide **1502** to an inside surface **8106** of the corset **7404**. In the cross-sectional view of FIG. **81**, the coupling spool **8104** has a barbell-shaped longitudinal cross-section. This reduced cross-section of elastomeric material reduces the amount of deflection of the waveguide **1502** when the jaw **7308** is clamping tissue against the waveguide **1502**. The relatively thick cross-section of the barbell ends of the seal **8104** maintains a water tight seal when the middle section of the waveguide **1502** deflects during clamping. A non-metallic material such as, but not limited to, Ultem, PTFE, Rulon, and Graphite filled materials may be used as the rigid coupling spool **8104**. The coupling spool **8104** being rigid limits the amount of waveguide **1502** deflection with respect to the jaw **7308** while still providing a non-metallic waveguide support and seal. It is important to design an interference to account for the deflection of the waveguide **1502** under such clamping forces. Deflection of the waveguide **1502** is a combination of bending and compression of the distal seal (**7404**, **7406**). Even though the distal seal configuration minimizes a thickness of elastomeric support, deflection of the waveguide **1502** still can be substantial. If an initial contact between the waveguide **1502** and the jaw liner **7314** was parallel, the waveguide **1502** would deflect and a gap would open at the root of the jaw **7308**. Therefore, the clamping assembly configures the initial contact to apply force at the root of the jaw **7308** and to later be parallel with the waveguide **1502** when the full clamping force is applied. With the aforementioned rigid material in the coupling spool **8104**, the deflection and variation in parallelism is minimized. Also present in FIG. **81** is an inner sleeve **7610**, which encircles the waveguide **1502**. As set forth below in detail, the sleeve **7610** assists in preventing metal-to-metal contact between the waveguide **1502** and the inner tube **7402**.

FIG. **82** provides a perspective view of an embodiment of the coupling spool **8104**. In this view, an interior surface **8202** of the coupling spool **8104** can be seen. This interior surface **8202** is in direct physical contact with the waveguide **1502** when the waveguide assembly **304** is assembled, as shown in FIG. **81**, for example. The perspective view of FIG. **82** also reveals an exterior saddle shape **8204** of the coupling spool **8104** that substantially corresponds to the interior shape of the saddle **7426**, which is illustrated in FIG. **81** too.

To help capture and retain tissue between the jaw member **7308** and the waveguide **1502**, the jaw member **7308** includes a liner **7314** having a plurality of teeth **7316**. This liner **7314** provides the jaw member **7308** with an increased ability to grip the tissue. This liner can be made of multiple non-metallic, high-temperature, lubricious materials such as, but not limited to, VESPEL®, RULON®, Modified PTFE, and glass filled and graphite filled versions of these. An exemplary embodiment of the liner **7314** is shown in the perspective views of FIG. **84** (from a distal-most end of the liner **7314**) and FIG. **85** (from a proximal-most end of the liner **7314**). In addition to the plurality of teeth **7316**, the liner **7314** includes a distal-most surface **8402**, a central smooth channel **8404** located between first **7316*a*** and second **7316*b*** longitudinal rows of the plurality of teeth **7316** on a lower surface **8403**, a flat proximal clamping surface **8405**, and an upper flange **8406** for securing the liner **7314** to the jaw member **7308**. This central smooth channel **8404** may also contain a groove **10014** that originates from the proximal end and runs distally as shown, for example, in FIG. **100**. This groove acts as an alignment feature between the liner **7314** and the waveguide **1502**, which aids in evening the effect upon tissue while using the device. The distal-most surface **8402** is, as can be seen in FIG. **73**, an exposed blunt front surface of the distal end of the waveguide assembly **304**. FIG. **73** illustrates a channel **7318** of the jaw member **7308** in which the liner **7314** is disposed when assembled. The inner surfaces of the channel **7318** substantially correspond to the outer surfaces of the upper flange **8406** so that the liner **7314** may be retained in the jaw member **7308** in a substantially movement-free manner. In the exemplary embodiment of the channel **7318** illustrated, the distal end of the channel **7318** is narrower than the intermediate portion so that the liner **7314** may slide from a proximal end of the jaw member **7308** up to but not past the distal end of the channel **7318**. Also shown in the exemplary embodiment of FIG. **85** is a retaining tab **8502** that, when the liner **7314** is placed in the jaw **7308** all the way distally, can be bent downward (towards the liner **7314**) and below the top plane of the liner **7314**. In such a bent configuration, the distal end of the retaining tab **8502** will oppose, and possibly rest against, the rear surface **8504** of the liner **7314** and/or flange **8406**. With such an opposition, the liner **7314** is prevented from exiting the jaw **7308**. This single retaining tab could be replaced with two smaller tabs on either side of the channel **7318** that are bent downwards below the top plane of liner **7314**. Alternatively, the jaw liner **7314** can be made to be loaded from a distal end of the jaw **7308** with features that capture and retain the liner **7314** through a single surgical procedure. An exemplary embodiment of such a configuration is shown in FIG. **100**. More specifically, the jaw **7308** is formed with a distal-entry passage or channel **10002** in which the distal-loading liner **10010** is loaded. To secure the liner **10010** in the channel **10002**, the channel can define orifices **10004** that are shaped to catch and removably hold therein detents **10012** of the liner **10010**. These opposing features can be reversed or changed in any equivalent way that removably secures the liner **10010** in the jaw **7308**. Easy replacement of the liner **10010** allows for potential reprocessing of the handle and/or waveguide assembly with an easy change of this high-wear part for potential reprocessing of the device.

The offset between the proximal-most surface **8402** and the flange **8406**, shown in FIG. **84**, facilitates the placement of proximal-most surface **8402** at the distal most portion of the jaw member **7308**. That is, the liner **7314** slides within the jaw member **7308** until it is fully seated within the jaw member **7308**. It is, however, the flange **8406** that is physically secured by the jaw member **7308**. More specifically, as is shown in FIGS. **84** and **85**, the flange **8406** extends beyond the plurality of teeth **7316** on both sides thereof. However, the flange **8406** does not extend all the way to the proximal-most surface **8402**. When the liner **7314** is slid inside the jaw member **7308**, the extending side portions of the flange **8402** travel within the channel **7318** formed in the jaw member **7308**. Because the flange **8406** does not extend all the way to the proximal-most surface **8402**, when the flange **8406** reaches the end of the channel **7318**, the proximal-most surface **8402** of the liner **7314** will extend beyond the channel **7318** up to the position shown in FIG. **73**.

Focusing now on the exemplary embodiment of the teeth **7316**, it can be seen in FIGS. **84** and **85** that the teeth **7316** do not extend completely across the lower surface **8408** of the liner **7314**. Instead, in the embodiment of FIGS. **84** and **85**, a first row of teeth **7316***a* and a second row of teeth **7316***b*, which oppose the first row of teeth **7316***a*, are separated by a central smooth channel **8404**. The central smooth channel **8404** provides a solid smooth surface that lines up directly over the waveguide **1502**. It is this smooth surface **8404** that comes into contact with the ultrasonically-moving waveguide **1502** during a procedure and helps seal the tissue by facilitating continued, non-impeded, ultrasonic movement of the waveguide **1502** with even pressure along its length. Due to the fact that the liner **7314** runs the full length of the jaw **7308** (from the root to the tip), contact over the entire length of the treatment portion (i.e., the blade portion **7304**) of the waveguide **1502** is made with even pressure.

Moving now to FIG. **86**, a fragmentary perspective view of an interior of the handle portion **302** is illustrated. This view shows a proximal-most end **8601** of the waveguide **1502**, which features a set of threads **8604** used to couple the waveguide **1502** to the TAG assembly **303**. As described above, the illustrated location of the proximal-most end **8601** of the waveguide **1502** within the handle portion **302** is substantially the location where the waveguide assembly **304** remains when it is coupled to the TAG assembly **303**. When the TAG assembly **303** is inserted into the handle portion **302**, see, for example FIG. **45**, the transducer horn **5002** aligns with and thereby allows a secure longitudinal coupling of the threads **8604** and the ultrasonic waveguide couple **5004**.

The waveguide **1502** is surrounded by the inner tube **7402** and, then, the outer tube **7302**. This view of the proximal-most end **8606** of the outer tube **7302** shows that the outer tube **7302** terminates at its proximal-most end **8606** with a flared section **8608**. The flared section **8608** features a pair of channels **8610** and **8612** (**8612** not fully shown in this view) forming a keyway. These channels are shown as opposing but need not be in this configuration. Residing within the channels **8610**, **8612** is a torque adapter **8602** that is fixedly coupled to the waveguide **1502**. The coupling of the torque adapter **8602** and the waveguide **1502** will be shown in more detail in the following figure, FIG. **87**. Continuing with FIG. **86**, it can be seen that the torque adapter **8602** is provided with a boss **8616** that extends out through the channel **8610**. Although not shown in this view, the torque adapter **8602** is also provided with a second boss that extends likewise within the second opposing channel **8612**. Engagement between the bosses **8616** of the torque adapter **8602** and the channels **8610**, **8612** of the flared section **8608** provides a rotational-locking relationship between the waveguide **1502**, the inner **7402**, and the outer tube **7302**. That is, because the bosses engage the channels **8610**, **8612**, any rotation of the waveguide **1502** is shared by both the inner tube **7402** and the outer tube **7302**. The proximal end of the inner tube **7402** does not extend past the torque adapter **8602**. The rotational connection between the torque adapter **8602** and the inner tube **7402** occurs through an internal feature of the waveguide rotation spindle **3704**.

Focusing now on FIG. **87**, a perspective view of an interior of the handle portion **302** is once again illustrated. In this view, however, the outer tube **7302** has been removed (along with a right half of the waveguide rotation spindle **3704**). The removed outer tube **7302** exposes a majority of the torque adapter **8602**. Although not viewable in either FIG. **86** or FIG. **87**, the torque adapter **8602** is, in one exemplary embodiment of the present invention, symmetrical with a second boss extending in a direction substantially directly opposite the first boss **8616**. The reason why the torque adapter **8602** is so-named is because it provides the structures for resisting rotational movement when the torque wrench **8800** is used to connect the waveguide coupler **5004** of the transducer horn **5002** to the waveguide **1502**. As described above, rotation of the waveguide **1502** needs to be prevented as the torque wrench **8800** is used to rotate the spindle **3704** of the transducer **902**.

To get an adequate holding force, the waveguide **1502** needs to be rotationally keyed. But, any rotationally keyed waveguide feature suffers from same drawbacks as other supports along the waveguide **1502** in that vibration is transmitted if the keyed feature is not located on a node of the waveguide **1502**. As shown in FIGS. **86** and **87**, for example, the keyed feature for torque transmission is located at the most proximal node, i.e., the node furthest from the blade and closest to the threads. The torque transmission feature of an exemplary embodiment of the invention is a plurality of splines or teeth **8702** in a radial pattern symmetrically disposed about the waveguide **1502**. Each spline **8702** extends away radially from a central longitudinal axis **8706** of the waveguide **1502**.

The torque adapter **8602** is provided with a plurality of interior keyways **8704**, each keyway **8704** aligning with one of the extensions of the spline **8702** and having a shape substantially corresponding to a respective one of the splines **8702** so that, when connected as shown, the torque adapter **8602** securely rests at its shown longitudinal position on the waveguide **1502**. This longitudinal position on the waveguide **1502**, too, is located at an ultrasonic vibration node where movement is minimal/non-existent. This aligning and securing engagement between the keyways **8704** and the splines **8702** places the keyways **8704** and the splines **8702** in a fixed rotational relationship. In other words, as the waveguide **1502** rotates, so too must the torque adapter **8602**.

The splines **8702** each protrude beyond average diameter of the waveguide **1502**. The splines **8702** can be rectangular columns but they are not limited thereto; they can have angled faces. One exemplary embodiment of the splines **8702** has an overall shape of a frusto-rectangular pyramid but with the two side edges of the top plane being sloped and the distal and proximal edges of the top plane being square. The maximum spline outer diameter can be kept within the largest diameter of the waveguide material to allow for use of stock material having the lowest cost. The torque transmission splines **8702** on the waveguide **1502** are mated to the torque adapter **8602** with correspondingly shaped female keyways **8704**. Assembly of the torque adapter **8602** occurs by pressing it onto the waveguide and finally to be constrained concentrically by the torque transmission faces of the splines **8702** and longitudinally by providing the keyways **8704** as blind holes, here on the non-illustrated end of the torque adapter of FIG. **87**. To rotationally align the torque adapter **8602** with respect to the waveguide **1502** and always place the bosses **8616** inside a pocket **9504** of the spindle **3704** (see, e.g., FIG. **95**), in an exemplary embodiment, some of the splines **8702** are removed selectively to permit only one correct component orientation (that can be symmetric but keyed to only be at 0 or 180 degrees). As such, when connecting the transducer **902** to the waveguide **1502**, the spindle **3704** is grounded (e.g., by the user's hand) torque is generated on the spinner **3704** by the torque wrench **8800**. The bosses **8616** are loaded and transmit the torque to the threads **8604** of the waveguide **1502**. Overall geometry and mass of the torque adapter **8602** are tuned to reduce acoustic coupling from the waveguide **1502** through the torque adapter **8602** to the spindle **3704**. The materials of the spindle **3704** and the torque adapter **8602** are selected to be different to further isolate any acoustic energy coupling. For example, a high-temperature, glass-filled polymer Radel (20% glass filled polyphenylsulfone PPSU) can be used for best acoustic energy impedance while still providing strength for torque transmission. A polymer filled with low friction materials such as Nylon or PTFE (Polytetrafluoroethylene) is also advantageous when minimizing acoustic transmission. In addition, an elastomeric material can also be insert molded into the spindle **3704** at the torque transmission face to further isolate acoustic energy.

Referring back now to FIG. **66**, it can now be seen that the channels **8610**, **8612** of the flared section **8608** of the outer tube **7302** are the features that also engage the rotation-prevention wheel **6502**. Due to this engagement, any rotation imparted on the waveguide rotation spindle **3704** by the user will result in a direct and corresponding rotation of the rotation-prevention wheel **6502**, the outer tube **7302**, the inner tube **7402**, the torque adapter **8602**, and the waveguide **1502**. The following is a result of this connection configuration: when the rotational lockout number **6508** is engaged with the rotation-prevention wheel **6502**, not only is the rotation-prevention wheel **6502** prevented from rotating, so too is the entire waveguide assembly **304**, **3704**, **7302**, **7402**, **8602**, **1502**. In the same sense, when the rotation-prevention wheel **6502** is not engaged with the rotational lockout number **6508**, a user can freely rotate the spindle **3704**, which is physically coupled to the rotation-prevention wheel **6502**, and cause a rotation of the waveguide assembly **304** along a longitudinal axis **8706**.

As shown in FIG. **95**, the spindle **3704** has oval bosses **9502** on its interior. These bosses **9502** engage both the inner **7402** and outer **7302** tubes, which locks the tubes **7302**, **7402** together rotationally while allowing only the inner tube **7402** to have longitudinal displacement. The area in which the bosses **9502** lock the tubes **7302**, **7402** is shown well in FIG. **93**. Looking at both of FIGS. **93** and **95** together, it can be seen that the protrusion of the boss **9502** is configured to enter the opening of the inner tube **7402** but not pass therethrough (to possibly contact the inner sleeve **7610** or to press the sleeve **7610** into the waveguide **1502**). At the same time, the bosses **9502** are shaped to have a longitudinal length sufficient to prevent longitudinal displacement of the inner tube **7402** but to permit longitudinal translation (proximal-distal) of the outer tube **7302** for moving the jaw **7308**. This complex locking feature, in conjunction with a pocket **9504** on a proximal end of the spindle **3704** that engages the torque adapter **8602**, locks the tubes **7302**, **7402** and the waveguide **1502** with respect to one another. In the exemplary embodiment, the torque adapter pocket **9504** has crush-features **9506** that force the torque adapter **8602** to center during assembly. Also in the pocket **9504** is a boss **9508** that traps the waveguide **1502** and prevents it from pulling out proximally. Assembly of the spindle **3704**, therefore, occurs by pressing two hermaphroditic spindle halves together. Once pressed together, it is desirable to have minimum friction between the mating rotational faces: the exterior of the intermediate annular groove **4610** of the waveguide rotation spindle **3704** and the annular boss **4605** of the handle halves **4503**, **4603**. As shown in FIGS. **95** and **99**, the mating rotational faces have a minimized contact area by chamfering the outer edges of the groove **4610** to set back the castellations on the proximal size and the finger grooves on the distal side of the spindle **3704** and by raising those contacting surfaces in the center of the groove **4610**. Likewise, the outer faces of the boss **4605** are raised at the center portions thereof.

As can be seen from FIGS. **73**, **74**, and **78**, and especially FIG. **84**, the lower surface **8403**, including the proximal clamping surface **8405**, is flat and parallel to the upper surface of the blade portion **7304** of the waveguide **1502**. This means that, when the jaw **7308** is clamped shut without any interposing material, the clamping surface **8405** will contact the blade portion **7304** at its proximal end first, as shown in FIGS. **79** and **80**. As such, when the waveguide **1502** is ultrasonically actuated, it is possible for the blade portion **7304** to cut into the liner **7314** at least to a point the two parts are parallel as shown in FIG. **89**. In the exemplary configuration of the jaw control device, however, it is possible for the jaw **7308** to pivot past parallel with respect to the waveguide **1502**. Therefore, it is possible for the blade portion **7304** to cut entirely through the liner **7314**. In such a case, the metallic blade portion **7304** would be vibrating against the metallic jaw **7308**—a condition that is to be avoided as either or both parts will break within a short period of time.

An exemplary embodiment of the inventive system solves this problem by including an overstroke prevention device **9002** and outer tube stop **9012**. The overstroke prevention device is comprised of a bobbin **9004**, a nut **9006**, an overstroke spring **9008**, and a distal slider **9010**. The bobbin **9004** is longitudinally fixed to the outer tube **7302** and translates along with the outer tube **7302** as the outer tube **7302** is moved with respect to the inner tube **7402** and waveguide **1502**, the latter two of which are longitudinally fixed in position with respect to the handle assembly **302** as set forth above. An exemplary embodiment of the attachment mechanism for the bobbin **9004** is shown, for example, in FIG. **86**, where two opposing windows **8614**, **8618** exist in the proximal end of the outer tube **8608**. The bobbin **9004** has a mushroom-shaped head **9602** on its distal end and a threaded portion **9604** on its proximal end for receiving the nut **9006** thereon and is illustrated, for example, in FIGS. **96** and **97**. The nut **9006** and the bobbin **9004** are configured to have the nut tightened to a hard stop **9702** that, in conjunction with a consistent spring **9008** yields consistent clamp forces from device to device. The spring **9008** has a low rate so that variations in tissue thickness will still yield similar clamp forces. The low rate has a flatter force profile so, regardless of where the spring is on the profile, the user is as close to the desired force as possible. As illustrated in FIG. **97**, the mushroom-shaped head **9602** connects longitudinally to the outer tube **7302**, in this example, through two opposing windows. The slider **9010** is able to longitudinally slide upon the outer surface of the main body of the bobbin **9004** between the nut **9006** and the distal head of the bobbin **9004**. As such, with the overstroke spring **9008** disposed between the movable slider **9010** and the stationary nut **9006**, any movement of the slider **9010** will cause a compression of the spring **9008**. As an aside, during assembly of the waveguide **1502** and tubes **7302**, **7402**, the proximal section of the outer tube **7302** can compress, due to the elongated channel **8610**, **8612** that runs out to the proximal end of the outer tube **7302**. The compressed proximal end of the outer tube **7302** is able to fit into the distal opening **9606** of the bobbin **9004** and, in so doing, forces apart lockout fingers **9706** (radially outward). Once fully inserted, the outer tube **7302** returns to its normal full diameter. At this point, the fixed bosses **9502** in the bobbin **9004** engage distal windows **8620** in the outer tube **7302**. At the same time, two rigid bosses **9608** extending from the interior surface of the bobbin **9004** engage the two opposing windows **8614**, **8618** at the proximal end of the outer tube **7302** as the lockout fingers **9706** spring inwards to enter the opposing channels **8610**, **8612** at the proximal end of the outer tube **7302**. The inward movement of the lockout fingers **9706** prevents further compression of the outer tube **7302**, thereby locking the bobbin **9004** onto the outer tube **7302**.

A yoke **9014** connects the slider **9010** to the trigger **4606** as shown in FIGS. **90** to **92**. The progression of FIGS. **90** to **92** shows how the yoke **9014**, the slider **9010**, the spring **9008**, the bobbin **9004**, and the outer tube **7302** move as the trigger **4606** is depressed to close the jaw **7308**. The location where the yoke **9014** interfaces with the bobbin **9004** is a rotational interface and, therefore, it is desired to only have minimal friction forces that do not impede rotation of the spindle **3704**. Minimizing such friction is achieved by including bumps **9802** on the yoke **9014**. These bumps **9802** create a point-contact having a greatly reduced surface area for the bobbin/slider interface. In the trigger state shown in FIG. **90**, the trigger **4606** is unactuated and the jaw **7308** is in the open, steady-state position (see, e.g., FIG. **73**). In the trigger state shown in FIG. **91**, the trigger **4606** is partially actuated and the jaw **7308** is in the closed position shown, e.g., in FIG. **79**. In this position, the yoke **9014** has moved the slider **9010** proximally to compress the spring **9008** partially, thereby applying a proximally directed force to the nut **9006**. As the nut is fixed longitudinally to the bobbin **9004** and the bobbin **9004** is fixed longitudinally to the outer tube **7302**, trigger movement causes closure of the jaw **7308**.

It is at this point that further closing of the jaw **7308** (rotation towards the waveguide) is not desired. To prevent the force from further movement of the outer tube **7302**, an outer tube stop **9012** is located on an exterior surface of the inner tube **7402** as best shown in FIG. **93**. In such a configuration, any attempt to move the outer tube **7302** further in a proximal direction will require a corresponding movement of the inner tube **7402**.

But, the jaw **7308** and the blade portion **7304** are used to cut tissue disposed therebetween. This means that when the jaw **7308** is clamped shut, any load that is transferred into the blade portion **7304** from either tissue clamped by the jaw **7308**, or by the liner **7314** itself, will deflect the blade portion **7304** both as a function of compressing the sealing spool **8104** and of bending the cantilevered beam of the blade portion **7304**. As the blade portion **7304** is bent, its ultrasonic movement characteristics alter. It is, therefore, desirable, to prevent bending of the blade portion **7304** as much as possible.

When the trigger **4606** is closed, the spring **9008** is compressed. An exemplary nominal force spring load when clamped on nothing between the jaw **7308** and the blade portion **7304** is approximately 24 pounds. This load increases with the rate of the spring as the thickness of tissue in the jaw increases to a maximum, which, in this exemplary embodiment is approximately 28 pounds when the jaw **7308** is pinned fully open by the tissue. When clamped, any load that is transferred into the blade portion **7304** from the liner **7314** deflects the waveguide both as a function of compressing the distal sealing spool **8104** and of bending the cantilevered beam of the probe. The distal sealing spool **8104** compression creates a non-linearity in a force v. deflection curve at the beginning of compression, but once the load is over 10 pounds, the curve straightens out. FIG. **94** is a curve illustrating deflection of the waveguide blade portion **7304** as a function of input force. With the jaw **7308** fully clamped with no tissue, the load input through the spring is applied both into the clamping of the liner **7314** against the blade portion **7304** and into the outer tube stop **9012**. The stop **9012** is attached (e.g., welded) with a strength able to withstand the maximum load. The placing of the stop is done in an already assembled system. The stop is tuned by placing the stop while a measured force is applied to the system to take up all of the tolerances and deflect the probe appropriately. As can be seen from the graph, the blade deflects at 10 pounds of force and continues deflecting until approximately 16 pounds of load. At this point, the outer tube **7302** contacts the stop **9012**. As the load increases at the spring **9008**, the stop **9012** begins to resist further motion of the outer tube **7302**. Any further increased load starts to be entirely borne by the stop **9012**, with no additional load being imparted into deflecting the blade portion **7304**. Once the force on the spring **9008** reaches approximately 22 pounds, any further increase in load does not translate into additional deflection of the blade portion **7304**. On the other hand, however, as shown by the straight lines in the graph of FIG. **94**, the load transfer to the blade portion **7304** continues linearly without the stop **9012**, as does the deflection of the probe. This outer tube stop could be achieved in multiple configurations. In the exemplary embodiment shown, it is a fixed stop **9012** placed on the proximal end of the shaft assembly. This same affect could be achieved at the distal end. For example, a non-illustrated tab on the end of the outer tube **7302** or the inner tube **7402** can be bent into place and act as a stop against further jaw **7308** movement. Similarly, a non-illustrated tab on the jaw **7308** could oppose either or both of the tubes **7302**, **7402** that is bent to interfere with this tube set, the tab could allow for assembly where jaw is moved past horizontal but prevents jaw movement past horizontal after assembly. Also, as opposed to a bend tab, a weld or a punch can be used to create a feature that acts as the stop. Furthermore, similar stopping features could be incorporated into the plastic of the handle.

As the invention is used in a procedure, the liner **7314** can wear. Meaning that the jaw **7308** will be free to pivot towards the blade portion **7304**. This wear, therefore, allows the outer tube **7302** to translate proximally. With the stop **9012** in place, however, such motion is prevented and the position of the jaw **7308** relative to the outer tube **7302** quickly becomes limited (i.e., it cannot continue to pivot closer to the blade portion **7304**). However, since the blade portion **7304** has already deflected away from the jaw **7308**, the blade portion **7304** is made free to move less away from the jaw as the liner **7314** wears away. As this happens, the amount of blade deflection and force required to maintain that deflection declines. This reduction in force creates less friction and heating in the liner **7314** and prolongs the life of the liner **7314**. With the invention, the maximum amount of deflection of the blade portion **7304** is between 0.030" and 0.035". The available thickness of the liner **7314** is made to be similar. Therefore, in an abusive condition with extended use without tissue (i.e., empty jaws), the worn liner **7314** might allow the metal jaw to touch the blade portion **7304**, but after such wear the force between them will be minimal or non-existent.

As already describe herein, the waveguide **1502** is mechanically fixed in the handle portion **302** at the torque adapter **8602**—in a proximal area of the waveguide **1502**, it is fixed concentrically within the handle portion **302** and the waveguide assembly **304** both rotationally and longitudinally; it is also fixed concentrically at a distal area of the waveguide **1502** by a coupling spool **8104** that acts as a distal seal. When the blade of the waveguide **1502** is placed under load during cutting and/or sealing, this relatively long waveguide beam (even though it is made of titanium in the exemplary embodiment) bends and can potentially contact the inner tube **7402** and, in such a case, it is probable that the touching will occur at acoustically active points along the waveguide **1052**. When the waveguide **1502** is bent as such and is active, metal to metal contact occurs. Such contact causes audible high frequency sound (e.g., squeeling) and significant power loss by generating heat at the contact point. This contact is to be avoided. Accordingly, the invention provides a contact support in the form of a waveguide bump **5710** at the waveguide **1502**, more particularly, at various locations along the waveguide **1502**.

An ideal location for any contact/support along length of an active waveguide **1502** is at node locations. Node locations are points of high stress and no displacement along a standing acoustic wave generated by the transducer **902** in the waveguide **1502**. Node lengths are infinitely short sections and displace about nominal (i.e., natural) locations due to drift of resonance frequency of standing wave. The bumps **5710** are larger diameter sections of the waveguide **1502** that extend virtually all the way to the innermost tube in the waveguide assembly **304**. Because the nodes displace longitudinally about a note point due to the drift of resonance frequency of the standing wave, each bump **5710** is centered about the nominal/natural node locations and have longitudinal lengths that encompass any displacement of the node location. The larger diameter of the bumps **5710** relative to an outer diameter of the waveguide **1502** provides another advantageous feature. As is understood with regard to ultrasonic vibration in waveguides, an increase in diameter results in a reduction of waveguide displacement, referred to as an step of anti-gain and making node location less active. As such, if the bump **5710** possibly transmitted any vibration to what it was touching, the amplitude of the vibration would be reduced with respect to the remaining, narrower sections of the waveguide **1502**. The number of the bumps **5710** are chosen selectively and do not equal the number of node locations along the waveguide **1502** in the exemplary embodiment of the invention, which is illustrated, for example, in FIG. **57** where four bumps **5710** are present. A minimum quantity of the bumps **5710** is chosen for ease of manufacturing and to prevent the above disadvantageous contact.

Even though the node locations are less active at the bumps **5710**, the abovementioned metal to metal contact still can be an issue. Accordingly, to further prevent such contact, the invention provides an inner sleeve **7610** that encompasses the section of the waveguide **1502** within the inner tube **7402**. The sleeve **7610** is made out of a low-coefficient of friction, high-temperature material (e.g., Teflon, PTFE, HDPE, Polyethylene). As can be seen in FIGS. **81** and **99**, respectively, the sleeve **7610** is naturally fixed concentrically about the waveguide **1052** and is mechanically fixed against longitudinal translation by the torque adapter **8602** at a proximal end of the sleeve **7610** and by the sealing spool **8104** at the distal end of the sleeve **7610**. The sleeve **7610** has an inner diameter selected to only contact the waveguide **1502** at the bumps **5710**. The outer diameter of the sleeve **5710** is allowed to contact the inner surface of the inner tube **7402** but can be slightly smaller. An alternate configuration of the sleeve **7610** has the sealing spool **8104** and the sleeve **7610** as a single piece. These components can share material, providing the concurrent benefits of lower part count and simpler assembly. In this exemplary embodiment the integral distal spool **8104** and sleeve **7610** are constrained by the corset on the inner tube **7402**.

When assembled the cross-sectional diameters of the waveguide **1502**, the sleeve **7610**, the inner tube **7402**, and the outer tube **7302** are configured to allow an air gap for ETO sterilization, for example. Airgaps along the bumps **5710** also reduce the amount of acoustic energy that can be coupled to the sleeve **7610** from the waveguide **1502**. Further, due to the low coefficient of friction of the material that makes up the sleeve (e.g., Teflon, PTFE), the acoustic energy that ever is imparted to the inner or outer tubes **7302**, **7402** is virtually non-existent. As an alternative embodiment to the singular, smooth, tubular sleeve **7610**, a more complex sleeve can be included that entirely eliminates the need to place the bumps **5710** on the waveguide **1502**. For example, the sleeve **7610** can have longitudinally extending parts, e.g., two, clam-shell-like halves that surround the waveguide **1502** between the torque adapter **8602** and the sealing spool **8104**. Each half can have inwardly protruding bosses and outwardly protruding bosses. The outwardly projecting bosses do not entirely surround the two outer surfaces of the halves to create gaps at each outer support point. These gaps permit penetration of ETO sterilization gasses all the way from the distal end to the proximal of the sleeve on the outer surface next to the inner tube **7402**. The outwardly projecting bosses can be staggered. The inwardly projecting bosses, on the other hand, are configured to contact the waveguide **1502** only at the nodes. As the longitudinal lengths of the bumps **5710** are sufficiently large, the inwardly projecting bosses can have smaller longitudinal lengths and the overall longitudinal length of the halves can extend all the way from the torque adapter **8602** to the sealing spool **8104** and, if desire, one can be integral with the sealing spool **8104**. In this way, the sleeve remains longitudinally stable with the inwardly projecting bosses located on the waveguide nodes. Another configuration can have the sleeve be a blow-molded part with both the inwardly and outwardly projecting bosses and, yet another configuration has the sealing spool **8104** blow molded integrally with this sleeve.

All prior art node supports are greater than one in number and are fixed to the outer diameter of the respective waveguide with 100% contact (pressed, bonded, molded). As such, acoustic energy is always coupled to such supports, which results in a higher natural power draw and in high assembly complexity and manufacturing cost. In contrast, the bumps **5710** and sleeve **7610** waveguide support of the invention are simple and cost-effective. The sleeve's constraint and one-piece configuration lends itself to a far simpler and cost effective assembly. Also, the bump features are not far different than the average diameter of the waveguide **1502** and are less than the maximum diameter of the waveguide **1052** to make extra fabrication a non-issue.

Construction of the waveguide assembly **304** is described with reference to FIGS. **100** to **105**. Initially, the liner jaw **7308**, **10010** in inserted and secured in the jaw **7308**. See, for example, FIGS. **100** and **101**. The inner tube **7402** is shaped to be extended beyond the distal end of the outer tube **7302** sufficiently far to allow a flexing open (as shown by arrows A) of the clevis arms **7418**, **7420** for receipt therein (arrow B) of the opposing bosses **7408** of the jaw in the progression of FIGS. **101** to **102**. With the jaw **7308** assembled in the inner tube **7402**, the jaw **7308** is pivoted below the centerline of the tubes **7302**, **7402** and the inner tube **7402** is slid into the outer tube **7402** as shown in FIG. **103**. This presents the pivot control tabs **7411**, **7412** of the jaw **7308** into a position to enter the outer tube **7302**. The jaw is, as shown in FIG. **104**, pivoted open above the centerline of the tubes **7302**, **7402** while the pivot control tabs **7411**, **7412** are inserted into the openings **7311**, **7312** of the outer tube **7302**.

The waveguide **1502** is, then, inserted through the set of tubes **7302**, **7402** to, thereby, trap the jaw **7308** therein—because the jaw **7380** can no longer travel towards longitudinal centerline of the tubes **7302**, **7402** due to the presence of the waveguide **1502**. This final assembly position is illustrated in many figures of the drawings, for example, in FIGS. **73** and **76**. Use of isopropyl alcohol, for example, allows the waveguide **1502** to be slid through distal dumbbell seal **8104** with ease. Thereafter, the alcohol evaporates so that no residue remains at the dumbbell seal **8104**. As is apparent, this assembly process is unique because it does not require any operations other than mechanically positional joining. No welding, crimping, or deforming occurs nor are there needed any other parts for full assembly.

This assembly process has a significant benefit with regard to manufacture. Lubrication of the inner and outer tubes **7302**, **7402** can occur at the tube manufacturer and not on the clean room assembly line, which prevents any contamination arising from such joining. Before coaxially fitting the inner and outer tubes **7302**, **7402** together, the translating o-ring **7406** is placed in the corset **7404** of the inner tube **7402** and, then, the outer tube **7302** is slid onto the inner tube **7402** up to the o-ring **7406**. Lubrication is placed on the o-ring **7406** and the outer tube **7302** is moved with respect to the inner tube **7402** (or vice versa) to have the o-ring **7406** roll and translate within the corset **7404**. Moisture in the lubrication is allowed to dry, which leaves only lubricant between the tubes **7302**, **7402** and around the o-ring **7406**.

A common issue in developing displacement-dependant ultrasonic systems is the complexity and inaccuracies of measuring waveguide displacement. The most accurate measurement systems are laser vibrometers that cannot be calibrated by equivalent high-frequency dynamic standards and are expensive. One crude and simple calibration method is to observe displacement of reflected "spots" on the surface of a dynamic high-frequency system under magnification. Peak-to-peak displacement is observed and can be correlated to known length standards. The principal issue with magnification observation method is the randomness or inconsistencies of such "spots". In an exemplary embodiment of measuring waveguide displacement, the invention uses a controlled visual feature such as an intentionally applied spot, mark, artwork, machined hole, groove or the like to the blade portion **7304** of the waveguide **1502**. Placing such a feature on the blade **7304** increases precision of magnified displacement observation and measurement.

XV. Additional Safety Features

In an exemplary safety embodiment for any of the configurations of the invention, the system can have a safety mechanism grounding the surgeon using the device to the handheld ultrasonic surgical cautery assembly **300**. In the event the waveguide **1502** accidentally makes contact with the surgeon, the handheld ultrasonic surgical cautery assembly **300** senses this grounding and immediately ceases movement of the waveguide **1502**, thereby instantly preventing the surgeon from cutting him/herself. It is possible to provide a safety circuit that can sense contact with the surgeon and interrupt ultrasonic power delivery because the hand-held instrument **300** is not connected to earth ground. For example, a capacitive contact patch located on the handle assembly **302** is connected to a capacitive-touch sensing circuit (such as is used for capacitive switching and known to those in the art) and disposed to detect contact of the working tip with the surgeon. When such contact is detected, the drive circuit **904** of the instrument will be shut down to avoid applying cutting energy to the surgeon. Such a sensing circuit would be impractical in systems of the prior art, where the handpiece is connected to a large piece of earth-grounded electrical equipment.

Another exemplary embodiment allows the transducer to work in a receiving mode where vibrations in the waveguide are turned into a signal that the electronics of the device could monitor. For example, vibrations associated with blood flowing through a vessel could be detected and used to provide feedback to the user about the type of tissue that has been clamped. For instance, during clamping of the jaw, this detection is able to determine that significant blood flow existed just before clamping. A signal could alert the user that the device is clamped on heavy vasculature and, for example, that low power for sealing should be used. Alternatively, if heavy vasculature is detected, high energy activation could be prohibited as a safety mechanism.

In accordance with another exemplary embodiment of the present invention, after the battery assembly **301** is physically and electrically coupled to the handle assembly **302**, the handheld ultrasonic surgical cautery assembly **300** will not operate until the button **4608** is changed from a depressed state to a released state, i.e., actively placed into a non-depressed position. This feature prevents the handheld ultrasonic surgical cautery assembly **300** from operating immediately upon connection of the battery assembly **301** to the handle assembly **302**, which otherwise could occur if the operator was unintentionally depressing the button **4608** when connecting the battery assembly **301** to the handle assembly **302**.

Because the present invention is comprised of three interconnected but separable components (i.e., the battery assembly **301**, the handle assembly **302**, and the TAG assembly **303**), each having its own accessible (as well as selectively exposed) electrical connections, there is a danger of electrostatic discharge (ESD) occurring between or among the three separable components. Accordingly, an another exemplary embodiment, the invention employs an ESD protection strategy to prevent damage to the device and the possibility of latent failures. A wide range of solutions for implementing this type of protection is contemplated as being within the scope and spirit of the present invention. Examples include, but are not limited to, using discrete ESD protection components and spark gaps as well.

In yet another exemplary embodiment for protecting against injury or damage from the electrical components of the device, the battery cells may be positioned in such a way (e.g., inverted) that their connector tabs point away from the electrical boards. This configuration reduces a likelihood of creating accidental shorts, as well as allowing the use of a cell interconnect board, which facilitates the connection of the battery cell tabs to the circuitry.

As has been described, the present invention provides a small and efficient hand-held ultrasonic cutting device that is self-powered and, therefore, cordless, which eliminates entirely the expensive set-top box required by the prior art devices. Advantageously, the device of the invention allows a user to operate completely free of cords or other tethering devices. In addition to the advantages of reduced cost, reduced size, elimination of a tethering cord for supplying power and carrying signals, and providing a constant motional voltage, the instant invention provides unique advantages for maintaining the sterile condition in a surgical environment. As has been explained, the inventive device is comprised entirely of sterilizable components that are maintained wholly in a sterile field. In addition, all electronic controls of the inventive system exist within the sterile field. Therefore, any and all troubleshooting can take place inside the sterile field. That is, because the inventive device is not tethered to a desktop box, as required in the prior art, a user need never exit the sterile field to perform any function with the inventive handheld ultrasonic surgical cautery assembly **300** (e.g., troubleshooting, replacing batteries, replacing waveguide assemblies, etc.). Furthermore, the inventive two-stage button allows an operator complete control of any surgical task without requiring the operator to focus their visual attention on the instrument itself. In other words, the operator does not have to look to ensure (s)he is preparing to push the proper button, as only one button is used.

The invention also provides low-voltage or battery-voltage switching or wave-forming stages prior to the transformer voltage step-up stage. By "marrying" all of the frequency sensitive components within one place (i.e., the handle), the present invention eliminates any inductive losses that occur between prior art set-top boxes and hand pieces—a disadvantage suffered by all prior-art ultrasonic cautery/cutting devices. Because of the close coupling between the drive circuitry and the matching network **1012**, the overall power modification circuit is tolerant of higher Q factors and larger frequency ranges.

Although specific embodiments of the invention have been disclosed, those having ordinary skill in the art will understand that changes can be made to the specific embodiments without departing from the spirit and scope of the invention. The scope of the invention is not to be restricted, therefore, to the specific embodiments, and it is intended that the appended claims cover any and all such applications, modifications, and embodiments within the scope of the present invention.

What is claimed is:

1. A battery-powered, modular surgical device, comprising:
- an electrically powered surgical instrument interfacing with bodily tissue during surgery and requiring a pre-determined minimum amount of electrical energy to power the surgical instrument completely through a surgical procedure; and
- a power module assembly having:
  - at least one modular battery supplying power for the surgical instrument during use and having a current state of electrical charge; and
  - a control circuit electrically coupled to the at least one modular battery and to the surgical instrument and comprising a memory and at least one microprocessor:
    - the memory storing data regarding the pre-determined minimum amount of electrical energy; and
    - the microprocessor being programmed:
      - to monitor and determine the current state of electrical charge of the at least one modular battery;
      - to compare the current state of electrical charge of the at least one modular battery to the pre-determined minimum amount of electrical energy;
      - to permit the battery to discharge if the current state of electrical charge of the battery is above the pre-determined minimum amount of electrical energy; and
      - to maintain the battery in a non-discharge state if the current state of electrical charge of the battery is below the pre-determined minimum amount of electrical energy.

2. The surgical device according to claim **1**, wherein the at least one modular battery is comprised of a plurality of rechargeable energy storage cells.

3. The surgical device according to claim **2**, wherein the control circuit determines a current state of electrical charge of each of the plurality of rechargeable energy storage cells and to equalize the current state of electrical charge amongst the plurality of rechargeable energy storage cells.

4. The surgical device according to claim **1**, wherein the control circuit determines the amount of power being discharged from the at least one modular battery.

5. The surgical device according to claim **1**, wherein the control circuit determines the current state of electrical charge of the at least one modular battery prior to beginning the anticipated surgical procedure.

6. The surgical device according to claim **5**, wherein the control circuit determines the current state of electrical charge of the at least one modular battery upon completion of the last, most-recent surgical procedure.

7. The surgical device according to claim **1**, wherein the control circuit determines an internal temperature of the at least one modular battery.

8. The surgical device according to claim **7**, wherein the control circuit prevents any power from being discharged by the at least one modular battery if the internal temperature of the at least one modular battery exceeds a given temperature.

9. The surgical device according to claim **1**, wherein the control circuit determines an internal impedance of the at least one modular battery.

10. The surgical device according to claim **1**, wherein the power module assembly further comprises a protection circuit interconnecting the at least one modular battery and the control circuit through at least one connection path such that the protection circuit is a conduit between the at least one modular battery and the control circuit.

11. The surgical device according to claim **1**, wherein the surgical instrument is an ultrasonic surgical instrument.

12. A battery-powered, modular surgical device, comprising:
- an electrically powered surgical instrument interfacing with bodily tissue during surgery and requiring a pre-determined minimum amount of electrical energy to power the surgical instrument completely through a surgical procedure; and
- a power module assembly having:
  - at least one modular battery supplying power for the surgical instrument during use and having a current state of electrical charge; and
  - a control circuit electrically coupled to the at least one modular battery and to the surgical instrument and comprising a memory and at least one microprocessor:
    - the memory storing data regarding the pre-determined minimum amount of electrical energy; and
    - the microprocessor being programmed:
      - to monitor and determine the current state of electrical charge of the at least one modular battery;
      - prior to beginning an anticipated surgical procedure, to compare the current state of electrical charge of the at least one modular battery to the pre-determined minimum amount of electrical energy; and
      - to permit the battery to discharge if the current state of electrical charge of the battery is above the pre-determined minimum amount of electrical energy; and

to maintain the battery in a non-discharge state if the current state of electrical charge of the battery is below the pre-determined minimum amount of electrical energy.

13. The surgical device according to claim **12**, wherein the at least one modular battery is comprised of a plurality of rechargeable energy storage cells.

14. The surgical device according to claim **12**, wherein the control circuit determines the amount of power being discharged from the at least one modular battery.

15. The surgical device according to claim **12**, wherein the control circuit determines the current state of electrical charge of the at least one modular battery upon completion of the last, most-recent surgical procedure.

16. The surgical device according to claim **12**, wherein the control circuit determines an internal temperature of the at least one modular battery.

17. The surgical device according to claim **16**, wherein the control circuit prevents any power from being discharged by the at least one modular battery if the internal temperature of the at least one modular battery exceeds a given temperature.

18. The surgical device according to claim **12**, wherein the control circuit determines an internal impedance of the at least one modular battery.

19. The surgical device according to claim **12**, wherein the power module assembly further comprises a protection circuit interconnecting the at least one modular battery and the control circuit through at least one connection path such that the protection circuit is a conduit between the at least one modular battery and the control circuit.

20. A battery-powered, modular surgical device, comprising:

an electrically powered ultrasonic surgical instrument interfacing with bodily tissue during surgery and requiring a pre-determined minimum amount of electrical energy to power the surgical instrument completely through a surgical procedure; and

a power module assembly having:

at least one modular battery supplying power for the surgical instrument during use and having a current state of electrical charge; and

a control circuit electrically coupled to the at least one modular battery and to the surgical instrument and comprising a memory and at least one microprocessor:

the memory storing data regarding the pre-determined minimum amount of electrical energy; and

the microprocessor being programmed:

to monitor and determine the current state of electrical charge of the at least one modular battery;

to compare the current state of electrical charge of the at least one modular battery to the pre-determined minimum amount of electrical energy; and

to maintain the battery in a non-discharge state if the current state of electrical charge of the battery is below the pre-determined minimum amount of electrical energy.

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